O&G Magazine

Vol 14 No 2 Winter 2012

Evidence

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

Qlaira®...

the first and only oestradiol OC Pill indicated for heavy menstrual bleeding[1*]

*For treatment of heavy and/or prolonged menstrual bleeding in women without organic pathology who desire oral contraception.[1]

Qlaira®

oestradiol valerate / dienogest

MINIMUM PRODUCT INFORMATION
QLAIRA® oestradiol valerate / dienogest. INDICATIONS: Oral contraception. Treatment of heavy and/or prolonged menstrual bleeding in women without organic pathology who desire oral contraception. **DOSAGE AND ADMINISTRATION:** One tablet daily. **CONTRAINDICATIONS:** Presence or history of venous or arterial thrombotic/thromboembolic events (e.g. deep venous thrombosis, pulmonary embolism, myocardial infarction), cerebrovascular accident, prodromi of thrombosis (e.g. transient ischaemic attack, angina pectoris); presence of severe or multiple risk factor(s) for venous or arterial thrombosis; history of migraine with focal neurological symptoms; diabetes mellitus with vascular involvement; pancreatitis or a history thereof if associated with severe hypertriglyceridemia; severe hepatic disease as long as liver function values have not returned to normal; presence or history of liver tumours (benign or malignant); known or suspected sex-steroid influenced malignancies (e.g. of genital organs or breasts); undiagnosed vaginal bleeding; known or suspected pregnancy; hypersensitivity to active substances or excipients. **PRECAUTIONS:** Circulatory disorders; risk of venous or arterial thrombotic/thromboembolic events; diabetes mellitus; systemic lupus erythematosus; haemolytic uremic syndrome; chronic inflammatory bowel disease (Crohn's disease, ulcerative colitis); sickle cell disease; migraine; hypertriglyceridaemia; pancreatitis; hypertension; jaundice and/or pruritus related cholestasis; gallstone; porphyria; Sydenham's chorea; herpes gestationis; otosclerosis-related hearing loss; angioedema; liver function disturbance; chloasma; galactose intolerance, Lapp lactase deficiency, glucose-galactose malabsorption; bleeding irregularities; pregnancy, lactation. **INTERACTIONS:** Medicines that induce microsomal enzymes (e.g. cytochrome P450 enzymes), phenytoin, barbiturates, primidone, carbamazepine, rifampicin, oxcarbazepine, topiramate, felbamate, griseofulvin, St. John's wort (*hypericum perforatum*), HIV protease (e.g. ritonavir), nevirapine, antibiotics (e.g. penicillins, tetracyclines), CYP3A4 inhibitors (e.g. azole antifungals, ketoconazole, cimetidine, verapamil, macrolides, diltiazem, antidepressants, grapefruit juice, erythromycin), lamotrigine. **ADVERSE EFFECTS:** Headache, migraine, abdominal pain, nausea, acne, amenorrhea, breast discomfort, dysmenorrhoea, intracyclic bleeding (metrorrhagia), genital discharge, menorrhagia, uterine/vaginal bleeding, spotting, weight increased, blood pressure changes, vulvovaginal mycotic infection, emotional disorder, insomnia, libido decreased, mood changes, liver enzyme increased, fatigue. **DATE OF TGA APPROVED PRODUCT INFORMATION:** 10 November 2010.

Before prescribing please review full Product Information

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PBS Information: This product is not listed on the PBS

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Before prescribing please refer to approved Product Information.
Approved Product Information is available from Aspen Pharmacare.

PBS Information: This product is listed on the PBS as: antihypertensive, centrally acting agent.

Aldomet® Minimum Product Information

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References: 1. Therapeutic Guidelines: Cardiovascular 2008.

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O&G Magazine authorised by Dr Peter White The submission of articles, news items and letters is encouraged.

For further information about contributing to O&G Magazine visit: www.ranzcog.edu.au/publications/oandg-magazine.html

ISSN 1442-5319

Cover image 9261262 ©Shutterstock
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Evidence

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L.AU.WH.12.2011.0209

PBS Information: Restricted Benefit. Contraception. Idiopathic menorrhagia where oral therapies are ineffective or contraindicated.

From the President

Dr Rupert Sherwood
President

Welcome to the Winter issue of *O&G Magazine*, which takes 'evidence' as its theme. Winter's shorter days and colder weather (for those of us not fortunate enough to live north of Brisbane) can mean that we are left with the impression we are spending a greater proportion of our time at work, rather than play. Similarly, recent strategic planning at RANZCOG with respect to training and workforce issues regularly prompted discussion about working hours and the ubiquitous 'work-life balance'. I doubt the latter is a new concept, just the proportions are changing. Having recently changed my work location and type, moving from full-time private O and G practice in Hobart to a staff specialist position in an outer western suburb of Melbourne, I have had occasion to reflect on these issues.

While I would be expected to have a better-than-average understanding of the challenges inherent to maintaining a high-standard O and G training program (from my four years as RANZCOG Training Accreditation Committee Chair, before assuming the position of President), it was not until I was immersed in the daily avalanche of the obstetric service load in a busy public hospital that I truly appreciated this challenge. Providing the balance between service delivery (an essential quid pro quo for the jurisdictions that employ our Trainees) and quality training remains one of the foremost challenges for RANZCOG.

I recently attended the Australian Society of Gynaecologic Oncologists meeting in Sydney to speak on the subject of training in gynaecological surgery. Of particular interest to the audience was that revisions to the advanced training program might include a module for year 5-6 Trainees to learn 'advanced pelvic surgery'. This is in order to enable us to train a cohort of FRANZCOG graduates who can assist colleagues with complex benign pathology and the higher acuity obstetric problems, particularly the obstetric haemorrhage cases, for which the gynaecological oncologists currently get called.

Other options to address what is perceived by some as a lack of surgical confidence in newer O and G graduates (as documented in the study by Andreas Obermair in 2009) include more attention to structured learning around all operative teaching cases, the increased use of simulation and, perhaps most importantly, promoting an informal mentoring program whereby experienced Fellows provide advice and assistance to newer graduates during their formative post-FRANZCOG years.

The conditions behind the current surgical training challenges are here to stay – shorter hours, restricted access to public hospital beds and the medicalisation of gynaecology, to name a few. As a training body, RANZCOG has to acknowledge these problems and find solutions, rather than waste energy bemoaning the 'lack of skills' in Trainees and new Fellows.

Further afield, I was invited to attend a meeting in Cape Town hosted by the Committee of Medical Colleges South Africa (CMSA). As an academy representing 28 colleges (including dentistry), the CMSA held a meeting focusing on governance and the core business of the academies and colleges charged with training, assessing and providing ongoing learning to specialists across all specialist medical disciplines. Presidents and senior professionals (100 delegates in all) from a diverse spread of locations attended and topics included the governance of the various bodies, training and assessment issues (with, not surprisingly, some common themes despite very varied resources), continuing education and medico-legal issues. One very relevant session was on 'medical migration' and the problems faced by less-resourced nations with disproportionately high burdens of disease when their recent graduates in specialist medicine leave their homeland to practice in well-resourced settings such as ours.

From this meeting I gained very valuable insights into the real challenges facing nations with limited resources and often unstable government when it comes to providing both high-standard training and maintaining service delivery, often in situations that, as one RANZCOG Board member commented, 'we only have nightmares about.' The gradual development of professional relationships between both the South African Academy, CMSA and its African neighbours may well be a worthwhile objective for the next RANZCOG Council.

The July Council meeting will be the last meeting of the Seventh RANZCOG Council, with the Eighth Council taking office in November. The current Council members have been extremely hard working and have readily engaged in many aspects of College business, and I sincerely hope those who have completed an initial two-year term will re-nominate to enable continuity of committee expertise and uninterrupted continuation of valuable ongoing work.

March Council saw the election of Prof Michael Permezel as President-elect and I offer my congratulations to him on his success. Michael brings perhaps an unequalled longevity and breadth of experience in College activities to the leadership position as President and Chair of the Board for the Eighth RANZCOG Council, and I look forward to working with him in the role of Immediate Past-President during his term in the 'big chair'.

In the last two years, the new role of Immediate Past-President on Council has been a great success; Dr Ted Weaver has chaired several committees and working parties, the most notable being the Training Program Review (now Implementation) Working Party. Resolutions passed by Council in July 2011 are now being backed by revised regulations, drafted by Dr Peter White, and his executive team, with planned review by the Board and Council in July ahead of the first cohort of Trainees who are to commence in December 2012. The Training Program Review process has exemplified several key aspects of College business: firstly that RANZCOG can, as a professional and educational body, respond to the need for change in the way we go about our core business; and, secondly, that an enormous amount of 'background' work is required to ensure that the policies and directives of the Council are successfully translated into workable regulations, reliable assessment tools and educational resources that meet the governance standards of our organisation. For this the Fellowship owes a debt of gratitude to the CEO and his team.

Among the many other issues that occupy the day-to-day work of the Board and Council are the following:

- The CEO and I have been in discussion with the Medical Board of Australia (MBA) to clarify the protected status of the

terms 'specialist' and 'subspecialist' in the context of medical practitioners descriptions and advertisement of their scope of practice. It is understood that following specific training in a defined area of practice (such as subspecialty certification) the description 'subspecialist in .....' should be afforded protection under National Law.

- The budget for the 2012–13 financial year will be presented to the Board for approval at its meeting in May. Subscriptions for Fellows for the next year have been approved; the increase above normal CPI reflects two essential projects, both of which will entail significant outgoings for the College. The first is the re-accreditation of the College as a training and accrediting body (we have completed a ten-year accreditation period, the longest available from the AMC, and must now undergo an extensive paper and site-based review in 2013); and the second is a major upgrade of the ICT capability of the College. So much of our business is now conducted online, and this will only increase as we move to online CPD for members, a marked upsizing of the available e-learning for both Trainees and members, and further changes to administrative aspects of training such as electronic log-books and training records for Trainees.
- In response to several requests from Fellows who are retired or semi-retired (or planning either) the Board is examining the possibility of a new 'semi-retired' category of Fellowship, with a defined (reduced) scope of practice and appropriate modifications to both subscriptions and CPD requirements. This project has 'in principle' support from Council and the details are being progressed by the Board.
- Two new statements have been written by the Board and approved by Council: the first is a statement titled 'Attributes of a RANZCOG Fellow', which attempts to define the clinical, academic and professional attributes expected of both a newly graduated Fellow and also, within the acknowledged limitations of changing scope of practice as we move through our professional careers, those expected of a Fellow generally. The second statement is a Guide to Credentialing for Fellows. The Board believes that this critical area of ensuring that Fellows practise within a scope of practice appropriate to their current skills and training has been, to date, under-resourced and we hope this statement, while not comprehensive in itself, will act as a resource for Fellows who undertake the credentialing of their peers. Both these statements, along with other new and revised statements generated from the combined expertise of the Women's Health Committee, are available on the RANZCOG website: www.ranzcog.edu.au .

In closing, I am very pleased to inform the membership that RANZCOG has been successful in a bid to host a joint RCOG/RANZCOG international scientific meeting in Brisbane in 2015. Congratulations to Ted Weaver, Kylie Grose, Lee-Anne Harris and the Queensland team for this effort, and we look forward to a great meeting. I would also like to draw your attention to the inclusion of College House in Melbourne's Open House weekend (see page 74 for more details).

There remains much to be done before I hand over to the incoming President in November and, as always, I remain very grateful to my colleagues on the Board, all Councillors, College staff and all those members of RANZCOG who unstintingly give of their time and expertise to College activities.

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From the CEO

Dr Peter White
CEO

This column was written immediately following the Provincial Fellows' Annual Scientific Meeting, held in Mackay, Queensland. With some 190 attendees, including Fellows, Diplomates, midwives and medical students, this was an enjoyable meeting that highlighted issues unique to practice in provincial Australia, as well as those that are shared more widely. Indeed, an article shown to me by an attending Fellow from *Obstetrics & Gynecology* that was pertinent to matters being discussed could have as easily been written in relation to either New Zealand or Australia, although it was for the USA. Again, the meeting contained both a main plenary program and a series of workshops designed to meet the needs of a wide range of RANZCOG members. This approach provides education opportunities that meet the needs of a range of membership groups and enable a range of experiences and views to be heard at College meetings. As always, my thanks go to the RANZCOG members and staff who worked diligently to ensure the meeting was a success. The next Provincial Fellows meeting will be held in Mildura, under the guiding hand of Prof Ian Pettigrew in April 2013, and many attendees at Mackay indicated they are looking forward to the program of educational and social events that will be provided.

What a difference a day or so and one or two flights can make. While the so-called 'tyranny of distance' has certainly not been conquered from the perspective of equitable healthcare delivery in either of the countries that RANZCOG primarily serves, one can go from being cold and wet in Melbourne on the morning of ANZAC Day to spending that evening and the following day in Sydney for the second meeting this year of the Committee of Presidents of Medical Colleges (CPMC) and then on to the Provincial Fellows' meeting in Mackay.

The CPMC meetings now involve meetings of college presidents and CEOs in both joint and separate sessions on the same day. In addition to opportunities to consider matters important to the specialist colleges, these meetings also provide opportunities for briefings from a range of external stakeholders, including the opportunity to seek clarifying information and raise policy matters with the representatives present. One such stakeholder is the Medical Board of Australia (MBA), whose remit clearly involves a range of matters that are of particular relevance for the specialist medical colleges and their members. Some specific matters recently raised and/or clarified are brought to readers' attention below.

Following concerns being raised by a range of stakeholders, the Board has advised of clarifications in relation to the definition of 'practice' and the need or otherwise for registration in order to undertake a range of functions, including teaching and acting as an examiner for a body such as the Australian Medical Council (AMC). Essentially, rather than altering the definition of practice as currently used (which would have required a change to each of the registration standards that currently reference the definition and, thus, the approval of all of Australia's Health Ministers), the Board has issued clarifying advice in relation to this matter through a statement issued on 12 March 2012. The statement may be accessed through the Board's website and should be referred to by anyone unsure about the need to be registered with the MBA in order to undertake a particular activity.

The statement also contains information in regard to 'protected titles' and their use. In medicine, the titles 'medical practitioner' and 'medical specialist' are protected and it is an offence under the Health Practitioner National Law (the National Law), which underpins the National Registration and Accreditation Scheme (NRAS) for an individual to use these titles if they do not possess the qualifications necessary to qualify under the National Law. For example, all holders of the FRANZCOG are entitled to use the title 'medical specialist', as well as refer to themselves as a 'specialist obstetrician and gynaecologist'; again, a protected title under the National Law.

Additionally, the MBA recognises the existence of five fields of speciality practice in obstetrics and gynaecology, corresponding to the five subspecialties in which RANZCOG offers certification. Each of these fields of speciality practice has a protected title associated with it, for which it is an offence to use that title if the appropriate qualification (in other words, RANZCOG subspecialty certification) is not held. For example, it is an offence under the National Law for a FRANZCOG holder who does not possess certification in gynaecological oncology to call themselves a specialist gynaecological oncologist or similar terminology that implies such. The setting and maintenance of standards for practice in the five subspecialty areas is taken seriously by the College and is reflected by the protection afforded by the MBA. As such, the College will consider bringing to the attention of the Board any medical practitioner who, in its opinion, is intentionally using title(s) that are protected by National Law. Additionally, the College has been advised that such misuse may contravene other legislation, such as the Trade Practices Act, and the RANZCOG Board therefore asks that all Fellows be cognisant in regard to the use of protected titles in the speciality, particularly those relating to subspecialist practice.

Another major stakeholder in College activities is the AMC, with which the College interacts in regard to two major activities: accreditation of its training and CPD programs; and the assessment of specialist international medical graduates (IMGs). The former activity is conducted by the AMC for the MBA under the National Law, while the latter activity involves coordination of some aspects of the process by the AMC, with the College conducting the assessment process of individual specialist IMGs for the MBA, again under arrangements pursuant to the National Law.

I wrote in the previous edition of *O&G Magazine* about the upcoming accreditation of the College during 2013, and the College is currently addressing a range of internal recommendations in preparation for this activity. The President and I have written previously of the Australian Government House of Representatives inquiry into the processes and support associated with IMGs. The inquiry's report, Lost in the Labyrinth, has been tabled in parliament and the College will consider, of the 45 recommendations made in total, the recommendations contained in the report that are applicable.

By the time of publication of this issue of *O&G Magazine*, it is anticipated that the process of formulating the College budget for the 2012–13 financial year will have been completed. In organisations

such as RANZCOG this is seldom a straightforward activity, with an awareness of the expectations of the College membership for increased services and an equivalent desire to ensure these expectations are met. The previous 'From the CEO' column dealt with the likely costs that will need to be covered by the College over the next two financial years in relation to accreditation, as well as the formulation and acceptance by the College Board of a strategic plan for ICT and the costs associated with this plan. The plan covers initiatives ranging from hardware and software upgrades, to ensure reliable service delivery, as well as value-adding initiatives, such as online CPD to accompany the role out of a revised CPD program and online training initiatives, including e-portfolios for Trainees.

As is now standard practice for the College, a detailed analysis of budgeted expenditure in relation to income streams has been undertaken in order to arrive at a decision regarding proposed increases in College fees and charges for the budget period. There is always a desire to limit increases in membership subscription fees to an absolute minimum, with CPI increases the standard desired benchmark in any given year. However, given the activities mentioned above, the decision has been taken this year to increase subscription costs by an amount over CPI in order to ensure that the associated costs can be covered equitably across all membership groups. One aspect of College business that has again been highlighted, through the cost centre analysis undertaken to guide budget development, is the extent to which the College underwrites activities relating to the MRANZCOG/FRANZCOG Training Program. This activity is, of course, part of the *raison d'etre* for the existence of the College. This is appreciated by all associated with College governance. In recent years the annual fee for MRANZCOG/FRANZCOG Trainees has risen by an amount over CPI that has been relatively minor in relation to the amount it is supported by the College. That said, it is becoming apparent that the shortfall between the revenue from Trainees and the cost of providing associated services cannot continue to be underwritten and a more significant increase in the annual training fee for Trainees will be recommended to the College Council and Board for the 2013 training year in order to address what is, essentially, an unsustainable situation.

Trainees who enter the MRANZCOG/FRANZCOG Training Program in December, when the training year commences in New Zealand, will pay a different annual training fee from that paid by Trainees currently in the program. This is no different from the situation that occurred at the end of 2003, when the current training program underpinned by the RANZCOG Curriculum was introduced. Just as the different costs then reflected the different requirements of the two programs that were in operation, so will the different fees that will operate from December reflect the different requirements of the two programs.

The decision has been taken in relation to all Trainees currently in the MRANZCOG/FRANZCOG Training Program not to transition them to the requirements of the new program. The essential differences between the current program and the revised program, being introduced in December 2012, are such that a clear distinction between Trainees in the two programs is considered the most appropriate approach to take. However, one area of current activity is consideration of how to enable some aspects of the new program to be implemented for Trainees already in training. Examples of such aspects include the possibility for part-time training to be credited in relation to FTEs between 0.5 and 1.0, as well as the ability to enter subspecialty training from Year 5, depending on the requirements and decision of each individual subspecialty in this regard. The College is acutely aware of its responsibilities to Trainees and is intent on ensuring that training arrangements available to Trainees in the program are as flexible as possible.

The regulations applicable to the revised training program are in the final stages of drafting and it is anticipated that these will be available following the July meetings of the College Council, Board and associated committees. The regulations will reflect the operational aspects of the new training program and, as far as possible, will mirror regulations in place for existing Trainees, reflecting the principles previously published by the College as underpinning the new program. These principles: require completion of all aspects of 'Core' training, including the MRANZCOG written and oral examinations and the attainment of College Membership (MRANZCOG), before the commencement of 'Advanced' training; and see the introduction of 'modularised' Advanced training and the ability to commence subspecialty training in the first year of Advanced training (in other words, Year 5 of the training program).

The RANZCOG Research Foundation is advertising application details for the Fellowships and Scholarships that it awards, either from funds held by the Foundation or dispersed on behalf of other entities using the selection process and infrastructure of the Foundation. All RANZCOG Fellows resident in Australia are entitled to become members of the Foundation on an annual basis at no extra cost as a result of arrangements introduced to reflect the annual donation that the College makes to the Foundation. Fellows who wish to become a member for 2012–13 may do so online via the my.ranzcog member portal or by contacting Ms Lauren Patten at the College (lpatten@ranzcog.edu.au). This year the amount of funding available through awards from the Research Foundation – to assist research in a number of areas relating to women's and reproductive health – will total approximately AUD$230 000. In New Zealand, the College supports research funding through the Mercia Barnes Trust, with the most recent call for applications for research grants by the Trust indicating awards to the value of NZ$70 000 available.

The most recent meeting of the current RANZCOG Council elected Prof Michael Permezel to the position of College President for the period from the Annual General Meeting to be held in November 2012 until that to be held in November 2014. As such, Prof Permezel will Chair the RANZCOG Board for that period, as well as the Eighth RANZCOG Council that will operate concurrently pursuant to the College Constitution. The next meeting of Council in July will elect the remaining Board members (the remaining 'office bearers' – three Vice-Presidents and the Treasurer – as well as two other Board members who are not designated office bearers). I congratulate Michael on his election, following a long period of committed involvement with the College, and assure him and the wider College membership of the continued absolute support and commitment of College staff. Additionally, I wish all current Councillors who choose to nominate for election to the Board the best of luck.

Following the election of Board members in July, attention will then turn to election of Councillors to fill Council positions through each of the regional committees and the Provincial Fellows. Again, at the Provincial Fellows' meeting in Mackay, during an open forum session where the President and I spoke about College activities and took questions, I reiterated the need for members to become involved in College activities either formally, through bodies such as the regional committees, Council or Board, or less formally, through the wide range of College activities that require member contributions. Once again, the time is approaching when the opportunity to contribute to the College at a formal level presents itself and I warmly encourage anyone with an interest to take that opportunity.

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Evidence

What would Socrates think?

Prof Caroline de Costa
FRANZCOG

Welcome to the Winter issue of *O&G Magazine*, which takes evidence-based medicine (EBM) as its theme. This term first appeared in the early 1980s, and the concept has spread into the collective consciousness of all medical practitioners, including obstetricians and gynaecologists, so that it is now a truth universally acknowledged that our clinical practice, in principle at least, should always be based on 'the evidence'.

There is, nevertheless, still an emotive component to the term, as to some it seems to imply that before the arrival of EBM, medicine had no scientific basis, but was merely a matter of opinion with a healthy dose of paternalism: trust me, I'm a doctor.

This of course is not the case. Much of our current practice has its origins in the exciting scientific discoveries of the nineteenth century, but even these built on earlier scientific experimentation, stretching right back to the ancient Greeks. Socrates developed his dialectic method of inquiry – the Socratic method – while strolling and chatting on the Agora in the fifth century BC. The Socratic method breaks down a problem into a series of questions, the answers to which gradually distill the solution to the initial problem. The influence of this approach is most strongly felt today in the use of the scientific method, in which the first stage is the hypothesis. All scientific research, and therefore all our evidence, begins with the hypothesis, which is ultimately either proved or disproved. Socrates would be amazed at what he started.

It is facile though to assume that there exists an absolute truth, an answer to every medical problem, which can be found by simply conducting a randomised controlled trial (RCT) and applying the results to human beings. When the substance being tested in a RCT is a small white pill and the subjects are laboratory rats, or even consenting college students, the process is straightforward. But as *O&G Magazine* readers will be aware, when the subjects are, for example, pregnant women, things become more complex. Few women will agree to be randomised to undergo, or not undergo, such procedures as caesarean section – as many Australian researchers have found.

There is also the well-known tendency for researchers not to submit, and journals not to publish, negative or ambivalent research findings, so that these are less likely to constitute part of 'the evidence' in any particular field, despite their importance. As well, the use of evidence may be subject to social influences; in Japan it took 30 years for 'the evidence' about the combined oral contraceptive pill (COCP) to be accepted and the COCP made available to Japanese women, whereas 'the evidence' for, and acceptance of, sildenafil (Viagra) took just six months. For many people, not least women giving birth, there may be cultural factors that no amount of evidence can change, as the fascinating article by Tze Yoong Wong (see page 62) explains.

In this issue we have included contributions on these many facets of evidence-based practice and debate, from an impressive array of experts. We thank them all for taking the time to write for us, and hope that you enjoy reading the products. Also, with this issue, we welcome to our team Drs Gillian Gibson and Alexa Bendall. Alexa is our new Trainee representative, she also holds the DRANZCOG.

In the coming issues, you will see some new features in your *O&G Magazine*, including Phot*O&G*raph: a chance to visually illustrate some of the more unusual and fascinating aspects of our practice. If readers have an image they would like to submit, in the first instance, please email a low-resolution file to lwesthaven@ranzcog.au.edu .

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I'm a doctor, can you trust me?

A/Prof Stephen Robson
FRANZCOG

Is it time to turn the levels of evidence on their head and return expert opinion to its rightful place?

I am as guilty as anybody else of using the phrase, 'I know there's no evidence for this, but…' Registrars have certainly heard me say it. It rolls off the tongue like a confession or, rather, a confession in advance. I say it when I'm about to use a treatment, or perhaps even not use a treatment, when I think I've seen it work in the past and I'm trying to act in a patient's best interests. I probably have my fingers crossed for luck at the same time.

Saying 'there's no evidence for this' is a shorthand way of conceding that some form of therapy has not been subject to a randomised controlled trial (RCT). If you consult the 'levels of evidence' tables that abound, it would be easy to get the impression that basing a therapy on level-three evidence is as close to a mortal sin as a doctor can get at work. In the Australian National Health and Medical Research Council (NHMRC) classification of levels of evidence (see Table 1), 'expert opinion' doesn't even rate a mention. Slightly more accepting of experts, the UK National Health Service (NHS) has adopted the classification of the Centre for Evidence-Based Medicine of the University of Oxford (summarised in Table 2), where expert opinion is down at level D.

Where's your evidence?

Every practising doctor is familiar with some definition of evidence-based medicine. The typical definition is something like, 'the process of systematically reviewing, appraising and using clinical research findings to aid the delivery of optimum clinical care to patients.'[1] I can't think of a single health professional I work with who doesn't want to provide optimum clinical care to patients. If we accept the dictum that the best evidence of all is that from a systematic review of controlled trials, where does this leave us in the management of common conditions?

Something that many of you will have noticed is that when our patients have a bad outcome, the accepted port of call for litigation is the 'expert witness'. Full weight is given to the evidence provided by experts because, well, they're experts. They have a great deal of experience in managing patients and that is clearly important in patient care. Let's examine some common conditions – things each of us will manage regularly – and walk through the evidence contained in the Royal College of Obstetricians and Gynaecologists (RCOG) guidelines, because these helpfully provide the levels of evidence that inform the recommendations.

Antepartum haemorrhage

The RCOG green-top guideline on antepartum haemorrhage was updated in November 2011. I'll present a typical scenario. A woman telephones her general practitioner to report some bright bleeding at 30 weeks gestation. She is advised to present to a hospital for formal assessment, which she duly does. At the hospital, the woman is assessed by both a midwife and a registrar. A full history is obtained, then a general examination and abdominal palpation are performed. The fetal heart and maternal observations are taken; a gentle speculum examination is performed. A cardiotocogram (CTG) is run while the ultrasound is awaited. A Kleihauer test is ordered to determine whether there is any evidence of feto-maternal haemorrhage. The bleeding is certainly bright and heavier than spotting, so the woman is judged to be at increased risk of preterm delivery and given a course of steroids for lung ripening.

The bleeding in this case eventually settles and the woman is discharged. However, she is changed from the 'shared care' protocol to antenatal care at the consultant-led clinic. The pregnancy seems to be uncomplicated thereafter, and she has a spontaneous labour and normal delivery at term.

Such clinical events occur almost daily in most delivery suites across the country. You may be surprised to know that the management protocol described above is entirely based on either expert opinion or, at best, level C recommendations. Not

Table 1. The NHMRC table of levels of evidence.

Level I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
Level II	Evidence obtained from at least one properly designed randomised controlled trial.
Level III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
Level III-2	Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case control studies, or interrupted time series with a control group.
Level III-3	Evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group.
Level IV	Evidence obtained from case series, either post-test or pre-test and post-test.

Table 2. Levels of evidence table used in the NHS and RCOG guidelines.

A	Consistent randomised controlled clinical trial, cohort study, all or none, clinical decision rule validated in different populations.
B	Consistent retrospective cohort, exploratory cohort, ecological study, outcomes research, case-control study; or extrapolations from level A studies.
C	Case-series study or extrapolations from level B studies.
D	Expert opinion without explicit critical appraisal or based on physiology, bench research or first principles.

a high-level evidence-based recommendation to be found. Even when antepartum haemorrhage is heavy, undiagnosed and occurs intrapartum, there is no high-level evidence to guide us. How do we ever manage to steer women through such potentially serious and life-threatening clinical conditions, then?

Laparoscopy

Tens of thousands of laparoscopies are performed in Australia every year. There is wide acknowledgement that laparoscopic procedures are safe and clinically effective for many conditions. Let me detail another common scenario. A woman in her 30s presents with pelvic pain that is worsening and has not responded to simple analgesics, oral contraception and nonsteroidal anti-inflammatory drugs (NSAIDs). On examination, there is some tender nodularity on the uterosacral ligaments and you feel that pelvic endometriosis is the likely cause of her discomfort. You discuss laparoscopy with her and advise that because she is overweight, there is an increased risk of complications. As a specialist gynaecologist with an interest in laparoscopic surgery (and a member of the Australian Gynaecological Endoscopy Society) you have considerable skill and experience. In theatre, you insert the primary trocar using an open, Hasson technique to reduce the risk of injury. Secondary trocars are inserted carefully under direct vision. Puzzlingly, no endometriosis is detected and the pelvis is healthy. You can reassure the woman that no serious pathology has been discovered.

Sound familiar? Unfortunately for you, not one single action you took during the assessment, counselling and surgery for this woman as described here ranked any higher than a level C recommendation. I hope you're feeling embarrassed.

Casting the net wider

It is important to understand that many of the very fundamentals of our practice have little or no high-level evidence to back them up. Let me give you some examples of commonly accepted and acknowledged safe clinical management actions that are based upon little more than expert opinion:

- Waiting until ten completed weeks of gestation before performing a CVS.
- Administering antenatal steroids to women with a multiple pregnancy who are at risk of preterm birth.
- Giving un-cross matched O negative blood to a woman who is having a severe postpartum haemorrhage when there is no time for cross matching.
- Carefully assessing a woman (and her fetus) with a breech presentation at term before counselling her on whether to try for a vaginal breech delivery. And, incidentally, none of the standard manoeuvres for delivering a breech vaginally have anything more than level-three evidence behind them.
- If performing a curettage for miscarriage, submitting the products of conception for histology.
- Avoiding the use of saline (and using glycine instead) if hysteroscopic electrosurgery is performed.
- Simply observing small ovarian cysts in anticipation that many are physiological and will resolve.
- Excluding chlamydial cervicitis as a cause of 'breakthrough bleeding' in young women using the combined oral contraceptive pill.
- Advising women who are concerned about reduced fetal movements to attend hospital for assessment.
- Making sure the serum hCG level falls to non-pregnant levels after treatment of an ectopic pregnancy.
- Advising women with vulval itch and irritation to avoid irritants.

Indeed, a detailed survey of evidence-linked guidelines for virtually all of the common conditions we manage reveals that we are operating almost entirely on level-two evidence, at best. A great deal of what we do is simply expert opinion.

Why isn't all healthcare based on level-one evidence?

A colleague of mine recently remarked, flippantly I might add, that even the use of a partogram in labour has never been subject to an RCT. How can it be that something as fundamental to the management of labour in our society as use of a partogram seems to be based on nothing more than historical hangovers from the early 1970s? The answer is, of course, that such management is extremely effective – so much so, we don't even think to think about it. Some things are thus self-evident.

The problems with randomised controlled trials are well-described by Henry Murray elsewhere in this issue of *O&G Magazine* (see page 40). They are expensive and need to be properly funded to achieve adequate recruitment, gathering of the required data and appropriate analysis. They are difficult and challenging to run because ensuring that all of those contributing to the trial are aware of the inclusion and exclusion criteria, and the study protocols is a complex undertaking. It is often difficult to find a publisher for a trial where no difference has been shown between treatment strategies, so effort is concentrated on trials where a big 'bang for the buck' is anticipated. This also makes it tempting to look for differences that might be statistically significant, but not clinically relevant. If funding and ethics approval have been obtained for a large trial, there is a strong motivation to press on even when thoughtful clinicians begin to question the conduct of a trial. There are so many human factors that influence the conduct and reporting of even the most brilliantly conceived study.

Let's not get too despondent about evidence, though. Randomised trials are excellent for addressing simple questions and can provide intriguing and 'game-changing' insights. Who would have thought that erythromycin is so much better for prophylaxis than co-amoxiclav in the management of preterm prelabour rupture of the membranes?[2] Or that giving magnesium sulphate intravenously is such a simple and effective way of dealing with eclampsia?[3] Neatly run trials that address simple questions are definitely the way to go, but are actually rather rare.

Adverse outcomes or insights from basic science, can alert us to interesting conditions and treatments. What about a case series of Kaposi's sarcoma in homosexual men?[4] Who would have predicted that such an obscure and seemingly irrelevant bit of level-three evidence would have been the harbinger of the global catastrophe that is the HIV/AIDS epidemic?

How about the first report of a laparoscopically assisted hysterectomy?[5] A bit of level-three evidence if ever there was one. Now, studies of the role of laparoscopy in hysterectomy, all the way to total laparoscopic hysterectomy in endometrial malignancy, have been keeping several journals alive and in print for years.

Back to the expert

I have often thought it is a great pity that we can't have 'inclusion' and 'exclusion' criteria for our patients. Unfortunately, I'm usually duty bound to take a history from, examine, investigate and do my best to try to help every patient I'm asked to see. I'm even guilty of not minding my business and giving 'helpful' advice to my colleagues about managing their patients. Few patients are as well-defined as the subjects in a randomised study. Most not

only have the condition of interest, but other problems as well. They often have jobs, commitments, a life and opinions. They have experience of medical treatment in the past and have often spent an inordinate amount of time searching the internet to find information about their problems. Blindly assigning patients to one or other treatment arm is simply not possible much of the time.

Perhaps it is time that we stood up for low-level evidence again. Patients come to us because they know that we have experience in managing and helping with their problems. We can put all the other evidence in context, look at the patient in an 'holistic' sense and try to develop a plan that meets all of the patient's and, indeed, their family's needs.

There is no doubt that when we are dealing with issues such as the optimal management of a malignancy, which antibiotic regime is the safest for women with preterm prelabour rupture of the membranes or whether to use a mid-urethral tape or perform a colposuspension, it is very nice to have the results of a systematic review and meta-analysis of RCTs to guide us.

However, is it really better to recommend a woman try for a vaginal breech delivery if nobody has any experience in such deliveries? Is it better to use IVF to achieve a pregnancy or to advise a woman to lose weight, stop smoking and take regular exercise? The only way to answer these types of questions is to take the entire circumstances into account. The results of some large RCTs have profoundly changed the way we manage our patients – vaginal breech delivery comes to mind. Perhaps the time has come to look again at expert opinion and other lowly forms of evidence such as cohort and case-control studies and the dreaded case series. Once a randomised study has handed down its findings, it can be difficult to go back. Do you think anybody is going to get funding to have another look at breech management?

References and further reading

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The RCOG Green Top Guidelines are all available for download from: www.rcog.org.uk .
The NHMRC levels of evidence grading can be viewed at: www.nhmrc.gov.au/_files_nhmrc/publications/attachments/cp116_app_f_levels_evidence_recommendation_grading.pdf .
Visit the Oxford Centre for Evidence-Based Medicine (CEBM): www.cebm.net .

The Cochrane project

Dr Gillian Gibson
FRANZCOG

The origins of evidence-based healthcare began with collaborative work in perinatal medicine. This has evolved into a worldwide organisation, with a maintained database, that is readily accessible, promoting the use of up-to-date evidence.

The origins of evidence-based healthcare began with collaborative work within perinatal medicine. The value of systematic review of controlled trials was recognised more than 30 years ago. This has evolved into a worldwide organisation, with a maintained database, that is readily accessible, promoting the use of up-to-date evidence.

The earliest recollection I have of the Cochrane concept of systematic review of evidence was the 1989 publication Effective Care in Pregnancy and Childbirth (ECPC) by Chalmers et al.[1] The history of the evolution of the Cochrane collaboration predated this by some years.

British epidemiologist Prof Archie Cochrane first drew the medical profession's attention to a 'collective ignorance about the effects of healthcare' in 1972.[2] In an essay, in 1979, he stated, 'it is surely a great criticism of our profession that we have not organised a critical summary, by specialty or subspecialty, adapted periodically, of all relevant randomised controlled trials.' Prof Cochrane identified obstetrics as the least scientifically based specialty. The Cochrane Collaboration is named in honour of him for his significant contribution to the development of epidemiology as a science.

Collaborative work

The first collaborative work to systematically review controlled trials occurred in perinatal medicine. In 1978, the National Perinatal Epidemiology Unit in Oxford, UK, was founded to assemble a register of controlled trials. By 1985, over 3500 reports of controlled trials in perinatal medicine had been classified, the results published, publication bias investigated and unpublished controlled trials identified. Between 1985 and 1990, an international collaborative effort was underway to systematically review controlled trials in pregnancy, childbirth and the neonatal period. This culminated in the publication of ECPC as well as A Guide to Effective Care in Pregnancy and Childbirth and the *Oxford Database of Perinatal Trials* (*ODPT*). In 1992, The Cochrane Centre was established in Oxford (later renamed the UK Cochrane Centre) to facilitate systematic reviews of randomised controlled trials (RCTs). The Pregnancy and Childbirth Group and Subfertility Group was registered.

Corticosteroid trial

The well-recognised Cochrane logo has at its inner core a graphic representation of the outcome of a systematic review of data from a set of RCTs. The review analysed trials investigating the use of corticosteroids prior to premature birth. The first of the trials was published by New Zealand researchers Liggins and Howie in 1972.3 By 1991, seven more trials had been reported with the combined picture indicating strongly that corticosteroids reduce the risk of babies dying from complications of immaturity. The odds of these babies dying from complications of immaturity were reduced by 30–50 per cent. Before 1989, there had been no systemic review of the trials available and most obstetricians had not realised that the treatment was so effective.

Evidence-based medicine expands

Work in the perinatal field gave the impetus to progress the pursuit of evidence-based medicine. It has expanded to include most branches of medicine and related fields. These include over 40 groups ranging from oral health, inflammatory bowel disease, wounds, screening and diagnostic test methods dementia and cognitive impairment, tobacco addiction, cystic fibrosis, hepatobiliary and healthcare of older people, just to name a few. In 1995, an article in the Lancet had suggested, 'the Cochrane Collaboration is an enterprise that rivals the human genome project in its potential implications for modern medicine.'[4] In March 2012, the number of Cochrane reviews in the database exceeded 5000. There are more than 28 000 people working within the Cochrane Collaboration in over 100 countries, of whom 70 per cent are authors of Cochrane Reviews.

The Cochrane Collaboration

The Cochrane Collaboration is an organisation that is not for profit, established in 1993, to promote, produce and disseminate systematic reviews of healthcare interventions. The term 'collaboration' was used to denote that the organisation benefits from teamwork within many independent groups worldwide. It fosters good communication and open decision-making, reduces barriers to contributing and encourages diversity.

The Cochrane Library

The Cochrane Library is a collection of databases in medicine and other healthcare specialities provided by the Cochrane collaboration (and other organisations). At the core of the collection are the Cochrane reviews, a database of systematic assessments of evidence and meta-analyses that summarise and interpret the results of medical research. The aim of the library is to make the results of well-conducted controlled trials readily available and it is a key resource for evidence-based medicine.

Accessibility

Textbooks and review publications tend to become out of date and unreliable. The original Cochrane reviews were developed as electronic publications. Between 1989–92 six-monthly CD ROM disks were released to keep the information on systematic reviews updated in the form of an electronic journal: the *ODPT*.

The Cochrane Collaboration publications have been made available free to all residents by 'national provision' in several countries, including New Zealand, Australia, India, South Africa, the UK, Ireland, Scandinavian countries, Canada and Poland. There is free access in much of Latin America. All countries have free access to page abstracts of all Cochrane reviews and short plain language summaries of selected articles, the latter is a defining feature of the Cochrane database.

Funding

The Cochrane library is a subscription-based database, originally published by Update Software, now part of the Wylie online system. The funding of the organisation's central function is royalties from its publisher that come from sales of subscriptions. There are a large number of governmental institutional and private funding sources, but there is a policy to limit uses of funding from corporate sponsors.

The past and present

The Cochrane collaboration has over 50 groups of dedicated professionals (the Cochrane Review Group). The groups produce all the systematic reviews and protocols that are located in the Cochrane database of systemic reviews (Cochrane reviews). The collaboration 'achieves results by people co-operating with each other, setting aside self-interest and working together to provide evidence with which to improve healthcare.'

Our College has two Fellows who must be acknowledged for their past and ongoing involvement with the Cochrane Collaboration. Caroline Crowther, professor in the discipline of O and G, at the University of Adelaide, is a member of The Cochrane Pregnancy and Childbirth Group. She is a recipient of the prestigious Ann Anderson award for her contributions to the Cochrane Collaboration. She has recently co-authored 'Pregnancy and Childbirth', a pocketbook based on the Cochrane database.[5] Cindy Farquhar, clinical professor of O and G at the University of Auckland School of Medicine, is a co-ordinating editor of the Cochrane Menstrual Disorders and Subfertility Group. A recent Cochrane review she co-authored is 'Caesarean Delivery for the Prevention of Anal Incontinence.'[6]

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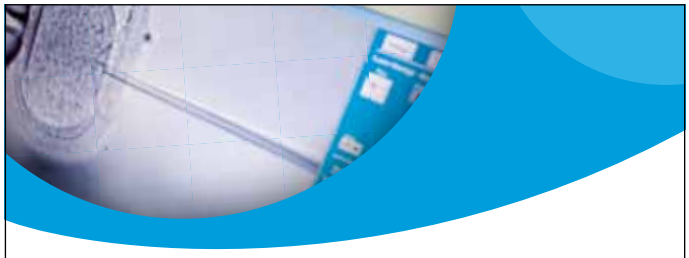

What evidence?

Some suggested rules for assessing the available evidence in women's health.

Prof Michael Permezel
FRANZCOG

Like all health practitioners, those in the area of women's health are obligated to use an evidence-based approach to clinical care. However, just what is the relevant evidence and how and by whom should it be interpreted?

Few practising obstetricians have not experienced frustrations following guidelines that derive from blind worship at the holy shrine of the randomised-controlled trial (RCT). Clinicians in other disciplines have had similar experiences[1,2] and such a restrictive interpretation of evidence is increasingly discredited.[3-5] With changes in the clinical workforce, a consortium of government, clinical networks and hospital administrators demonstrate an imperative to develop more and more clinical protocols and guidelines so that patient care may become driven by slavish adherence to a 'recipe' rather than by the thoughtful application of evidence by individual clinicians. It is therefore timely to ask just what evidence these bodies should be using and what directions should be pursued for future accumulation of evidence?

Rule 1. The RCT: often not the best evidence
The RCT has pride of place among levels of evidence as defined by the guideline development group from the National Health and Medical Research Council (NHMRC).[6] The Royal College of Obstetricians and Gynaecologists (RCOG) in their 'green-top guidelines' emphasises the privileged position of the RCT, a 'grade A recommendation' can only come from an RCT. Is this position in the hierarchy of evidence justified?

Rule 1.1. The under-powered RCT: a source of damaging false-negative conclusions
Where an RCT reports a negative result, it may well be that no clinically important difference exists. However, it is equally plausible that the study size was too small ('under-powered') and a clinically important difference was in reality present, but not demonstrated. Unfortunately, obstetrics is particularly prone to this phenomenon because very small differences in outcomes are clinically important to both patients and their carers[7] – meaning that massive sample sizes become necessary to detect clinically important differences.

Using only the RCT evidence, it is possible to (unwisely) conclude that an admission cardiotocograph (CTG) does not impact on fetal wellbeing.[8] The extremely low incidence of adverse outcomes in low-risk patients means that the RCTs have been under-powered with respect to admission CTGs and serious adverse neonatal outcomes. Having convinced the RCT 'enthusiast' that perhaps the RCT was under-powered to answer the issue of perinatal outcomes, the enthusiast then concludes: 'we do not know if it is beneficial or not.' Other evidence points overwhelmingly to the fact that early identification of the hypoxic fetus in labour will prevent further hypoxic damage or death as labour advances. It is almost as apparent as the need for a parachute when falling from a great height![4]

Rule 1.2. RCTs may lead to recommendations based on clinical protocols that are not in common practice
To achieve even a moderately acceptable sample size, it is frequently necessary to use multiple trial centres, sometimes across international boundaries. The trial protocol must then be able to accommodate the clinical vagaries of each centre, sometimes at the expense of almost invalidating the study with respect to making recommendations for common clinical practice.

In the 'Term Breech Trial', key management specifications were not directed in the trial protocol, including obligatory intrapartum CTG, a recent obstetric ultrasound and good progress in labour.[9] Each was left largely at the discretion of the managing clinician – despite the fact that a substantial body of opinion would require continuous cardiotocography in labour, a recent ultrasound to exclude head extension or abnormality, and would deliver by caesarean section if there was inadequate progress in labour.

Rule 1.3. RCTs may lead to recommendations that are not valid for particular subgroups
The RCT design must permit sufficient heterogeneity in the patients to have a realistic chance of achieving the targeted number of trial subjects. Inevitably this diversity among the study subjects will mean that any conclusion may not be applicable to specific sub-groups within that population. The Women's Health Initiative (WHI) trial still very much guides the use of hormone replacement therapy.[10] The attentive gynaecologist will be aware that this trial included many women with risk factors for atherosclerosis, including women over 70 years of age with hypertension, diabetes and hyperlipidaemia. Few clinicians would dispute that a pro-thrombotic drug (such as oral oestrogen) is undesirable in the presence of established atherosclerosis, given that thrombosis of the atherosclerotic plaque may lead to ischaemic injury of heart or brain. However, in the absence of established atherosclerosis, oestrogen may actually confer real benefits by improving the lipid profile and thereby reducing the occurrence of atherosclerosis in the first place. Yet, such has been the blind reverence shown to this so-called 'level I evidence', health practitioners have largely condemned HRT – perhaps at some considerable health cost to those women at very low risk of established atherosclerosis.

Rule 1.3.1. Subgroup analysis does not necessarily overcome the problems arising from a diverse population under study
Sub-group analysis has serious deficiencies.[11] Firstly, the sample size is smaller than the population itself, leading to an even greater likelihood of a type 2 error (missing a true difference). Just as importantly, analysis of multiple subgroups is a recipe for type 1 error (falsely reporting a difference when none really exists through multiple comparisons). If enough subgroups are analysed, some difference will eventually become significant.

This is not to say the sub-group analysis should not be performed. It is evidence that should join the complex coalition of all evidence in decision-making. The weight given to such an analysis will appropriately depend on such considerations as whether there was prospective definition of the sub-group analysis, the number of sub-groups assessed, the strength of the trend and the confidence limits of association. Whether a recommendation follows that trend, will depend on all other available evidence, as assessed by those best equipped to assess all evidence, something I address below.

Rule 1.4. RCT results may not be applicable outside the trial situation – The Hawthorn Effect

Diligent adherence to trial protocols and specific resources allocated to the clinical trials situation may well lead to outcomes that are valid within the study context, but are not replicated outside the trial situation. The infamous 'Dublin RCT of electronic fetal heart rate monitoring' has been used widely to infer that there is 'no benefit from continuous electronic fetal heart rate monitoring in the absence of risk factors for fetal compromise'.[12] Yet few labour wards in Australia or New Zealand come even remotely close to the management in that trial. All women in that study had their membranes ruptured on admission in labour revealing liquor that was both clear and adequate. They also had auscultation of the fetal heart rate for one minute 15-minutely in labour and after each contraction in the second stage. A dedicated midwife attended to each woman. Even with such vigilance, there were significantly more neonatal convulsions in the auscultation group and the primary hypothesis of adverse neonatal outcome came very close to clinical significance, with a p-value after adjustment of 0.08.

What, then, is the value of continuous electronic fetal heart rate monitoring in a labour ward where there is not a one-to-one midwife-patient ratio, where the colour of the liquor is unknown for a major proportion of labour and where auscultation of the fetal heart rate occurs half hourly at most and rarely for a full minute? Is it still reasonable to conclude that there is no benefit to continuous electronic fetal monitoring in low-risk labour? Clearly not. All evidence must be considered and that evidence applied to each clinical circumstance.

Rule 2. In making clinical decisions or developing a recommendation for clinical management, all evidence must be considered

Rule 2.1. In the absence of an RCT, it is wrong to conclude there is no evidence

The *BMJ* paper 'Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials'[4] perfectly illustrates how medicine does not depend on the clinical trial for all clinical guidance. There is other evidence in abundance. Physics can predict the effect of a high-velocity collision between two spherical objects. In the case of a collision between a human head and the planet earth, a clinical trial would seem to be unnecessary.

The clinical equivalents are almost unbounded in their number. Who would dare question the wisdom of treating a blood pressure of 300/160, a ruptured appendix or even prompt delivery in the presence of a sustained fetal bradycardia in the second stage of labour? Yet, these clinical decisions are not based on RCT evidence. Happily, the curriculum of RANZCOG and other specialist colleges continue to recommend a sound foundation in the scientific basis of their disciplines. It is distressing that a number of undergraduate medical curricula appear to have lost their way in this respect. An understanding of 'causation' underlies good clinical practice and in many ways defines 'medical' care.

Rule 2.2. 'Deterministic causation' – the most powerful evidence of all

The parachute against gravitational challenge, the ruptured appendix and severe fetal compromise in labour are all examples of deterministic causation. Broadly speaking, a strong rationale for causation can be established in a similar way to Robert Koch and his 'postulates' of 1890.[1] Having determined causation beyond reasonable doubt (for example, a bad outcome ensuing from head crashing into ground or conservative management of a cord prolapse in early labour), the need to avoid the causative insult is immediately evidenced.

Rule 2.3. Thou shalt not be overly dismissive of anecdotes

All dogs have tails. There is a tail, therefore it is a dog. The anecdotal observation of a cat (hopefully in possession of a tail), will disprove the statement that a tail means it is a dog, thereby demonstrating the power of a single observation. How often do we hear colleagues dismissive of a clinical anecdote? 'Provide some real evidence.'

A clinical tale (or tail) may not just be a useful learning experience, it may actually provide the best available evidence, sometimes more powerful than an under-powered RCT. In deciding on the wisdom of epidural anaesthesia in the presence of severe thrombocytopenia, just a single case report of a large epidural haematoma (with catastrophic sequelae), might be powerful enough evidence to dissuade the conscientious anaesthetist from embarking on neuraxial anaesthesia under such circumstances. The numerator in a single case report may be '1' but the denominator (epidural anaesthesia in severe thrombocytopenia) is not large, so the magnitude of the true risk may be of clinically relevant proportions.

Rule 2.4. Cohort, case-control and population studies are also often the 'best' evidence

So often these other sources of 'evidence' are dismissed in favour of a loosely relevant RCT. These studies are often based on vast numbers, sometimes population sizes that are unattainable in RCTs but, as stated above, necessary in order to guide management where it is appropriate that rare adversity guides clinical practice.

What is the perinatal mortality after 41.0 weeks gestation? What is the neonatal mortality after elective caesarean section at 39 weeks? At 38 weeks? What is the likelihood of perinatal death or long-term morbidity after caesarean section at term? What is the incidence of placenta accreta in subsequent pregnancies? All critically important questions that guide day-to-day clinical practice, but only ascertainable by population studies.

Rule 2.5. Clinical experience may be compelling evidence in itself

So much of the art of obstetric practice has its origins in the teachings of senior obstetricians handed down, generation after generation. From the application of forceps to the conduct of vaginal breech delivery, the techniques have been learnt by the experience of our predecessors. While it is undoubtedly both proper and essential to question established practice, it is even more wrong to discard it for 'lack of evidence'. Bayes' theorem recognises the imperative of placing a high value on established practices and the onus of proof applied to new alternatives should be considerable.

Rule 3. All guidelines and recommendations are the subjective opinion of their authors, based on their interpretation of the evidence they select

Clinical recommendations or guidelines are the result of an attempt to assess the evidence by a person, or more commonly a task group. The evidence is the study. The selection of evidence and application of that evidence to a clinical situation is interpretative and dependant on the knowledge, expertise and biases brought to the problem by those writing the guideline. It is concerning that a small group of 'clinical trials specialists' with little background knowledge and almost no clinical experience in the discipline can interpret RCT data and cite that opinion as 'level I evidence'. In contrast, the vast body of clinical experts in the field, in possession of untold knowledge, skills and experience, assessing all evidence (not just RCTs), have their opinion relegated to 'Level of Evidence: IV' and 'Grade of Recommendation: C' – with the implication that it is barely worth considering.

Any recommendation must be based on the careful selection and interpretation of the available evidence. The likelihood of incorrectly evaluating the available evidence will be minimised by confining recommendations only to those issues on which a broad consensus can be achieved. The perpetual tragedy of obstetrics is that those clinicians most experienced (and therefore most able to evaluate available evidence) will rarely have time to sit on a 'guideline development group'. Instead, guideline development groups are populated by epidemiologists and administrators – not necessarily the most worthy group to be determining clinical policy.

Rule 4. The Principle of Uncertainty: even in the presence of apparently overwhelming evidence, there always remains an element of uncertainty

On occasions, the available evidence may be overwhelming and the recommendation very strong. A clinical group may be so profoundly confident of their recommendation that an alternative approach could not be in any way countenanced. Yet there is always an element of doubt and health services should always be prepared to review recommendations and must exhibit a liberal toleration of diversity in clinical management. The door must remain open to allow continued accumulation of new evidence or an alternative interpretation of existing evidence. If evidence interpretation becomes clinical 'law', the continued accumulation of evidence is hindered.

Conclusions

The most useful evidence for determining clinical care is most often not an RCT – even when it exists. Recommendations should come from a complex coalition of relevant RCTs, cohort, case control and population studies combined with a plausible rationale – according to the principles of 'deterministic causation'. Ultimately, all recommendations are effectively expert opinion: the product of evidence selection and interpretation of the group making the recommendation. Importantly, those involved must possess the insight that comes from extensive clinical experience so they are able to assimilate all the available evidence in the most expert manner available. Only when these stars align can we ensure the highest probability of a valid recommendation.

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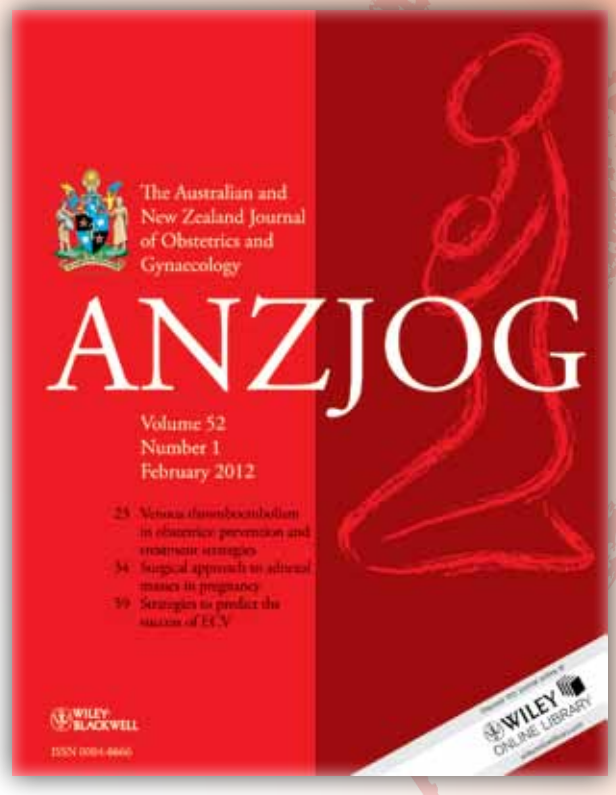

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12-40641

Trials and tribulations

The importance of testing interventions with randomised trials.

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Evidence-based medicine is a phrase that was coined in the early 1990s[1] and defined by David Sackett as 'the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients'.[2] However, the principal tenet underpinning evidence-based medicine can be identified much earlier. The French physician Alexandre Louis led an initiative termed 'medecine d'observation' in which practitioners were encouraged not to rely on 'speculation and theory about causes of disease nor…single experiences,' but rather to make a 'large series of observations and derive numerical summaries from which real truth about the actual treatment of patients will emerge.'[3]

According to the Oxford English Dictionary, 'evidence' simply refers to the available body of facts or information that indicates whether a belief or proposition is true or valid. In this context, therefore, virtually all clinicians use 'evidence' in making decisions about patient care, and perhaps we should be aspiring to a 'better use of evidence in medicine'.[4] There are numerous examples in contemporary obstetric practice where, as a specialty, we could have made 'better' use of the available evidence. Archie Cochrane, in his now well-known writings, awarded the 'wooden spoon' to obstetricians for having made the poorest use of randomised trials and having widely incorporated changes into clinical practice without appropriate evaluation[5], resulting in the widespread adoption of some practices of uncertain benefit (for example, continuous fetal heart rate monitoring during labour) and the delayed introduction of others (for example, the use of antenatal corticosteroids prior to preterm birth).

Many national research bodies have published hierarchy of research evidence, based on how well potential biases have been minimised (see Table 1), identifying systematic reviews of randomised trials and randomised trials to be of high quality. The randomised trial represents a 'gold-standard' methodology in assessing or comparing the effects of different treatments. However, randomised trials are not the only source of valid evidence, nor are they the most appropriate study design to answer all research questions. Furthermore, just because a study is designated as randomised does not imply that it is high quality or without methodological flaw. The following discussion will consider both the strengths and limitations of randomised trials.

The singular advantage of randomised trials is the random allocation of participants to the treatment groups being evaluated, ensuring that the distribution of both known and unknown subject factors that may influence treatment outcomes are randomly allocated across treatment groups. The result is the creation of groups that are similar in their baseline demographic and prognostic variables. Comparable treatment groups at the time of trial entry therefore means that any observed differences in outcomes are likely to reflect true differences between the treatment interventions, rather than individual subject differences.

A number of methodological steps are key to the process of random allocation, the generation of comparable treatment groups and, therefore, minimisation of selection bias. The first is the method of sequence generation, which can broadly be considered as those processes that are truly random and therefore have low risk of bias (for example computer-generated sequence; random number table), as compared with those that are non-random, potentially subject to manipulation, and therefore have high risk of bias (for example odd or even date; or hospital record number). Allocation concealment describes the processes whereby treatment allocation could have been foreseen in advance or potentially changed after recruitment has occurred. Methods considered to have a low risk of bias include use of a central telephone or web-based randomisation service, or sequentially numbered, sealed, opaque envelopes. In contrast, known allocation to treatment groups based on alternation, day of the week of presentation or participant date of birth would all be considered to be at high risk of bias. Failure to maintain random allocation and allocation concealment have been shown to result in overinflated estimates of treatment effects.[6]

Table 1. NHMRC Evidence Hierarchy: designations of 'levels of evidence' for intervention studies. Adapted from: NHMRC levels of evidence and grades for recommendations, December 2009.

Level of evidence	Description
I	A systematic review of level II studies
II	A randomised controlled trial
III-1	A pseudo-randomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: • Non-randomised,experimental trial • Cohort study • Case-control study • Interrupted time series with a control group
III-3	A comparative study without concurrent controls: • Historical control study • Two or more single arm study • Interrupted time series without a parallel control group
IV	Case series with either post-test or pre-test/post-test outcomes

Blinding, or masking, refers to the steps taken to ensure that the treatment group allocated remains unknown by participants and caregivers, and often involves the administration of a placebo. While in many circumstances, blinding of participants and their caregivers may not be possible, it is almost always possible to blind outcome assessors to the intervention received. The potential impact of masking varies with the outcome assessed, being particularly important in the evaluation of subjective measures (for example, experience of pain), but relatively less so in the evaluation of more objective outcomes (for example death). While studies are often described as 'double-blind', a more specific statement on who was blinded is preferable. Blinding attempts to reduce performance bias (or systematic differences in the care that is provided to participants other than the intervention under investigation), again ensuring any differences observed between the groups reflect differences in the treatment or intervention received.

The above methodological considerations reflect the internal validity of a randomised trial, while external validity refers to the extent to which trial findings can be generalised beyond the study environment to routine clinical practice. Consequently, generalisability is influenced by the similarity of the trial population to the broader population, the nature of the intervention (and, in particular, its relationship to current standards of care) and the outcomes reported.

Randomised trials often have clearly defined, rigorous inclusion and exclusion criteria and while this may create a relatively homogeneous trial population, the challenge then lies in demonstrating that the circumstances and results are applicable to a wider clinical population. An alternative approach has been suggested[7] in which the question is asked: 'Are there any good reasons to believe that the research is not relevant…if there are not…the default position should be that the result should be regarded as applicable.'

Further confounding the issue of generalisability is recognition that individuals who participate in randomised trials are inherently different to those who decline participation, often being of higher socioeconomic standing and higher educational attainment, both of which contribute to a tendency to greater compliance or adherence to the intervention. The net effect is therefore an overestimation of treatment effects when compared with what might be reasonably achieved in the general clinical population.

Similar concerns are often raised in relation to the nature of trial interventions, reflecting the importance of engaging clinicians, researchers and other stakeholders during the process of trial development. If trial interventions deviate significantly from those in standard clinical practice, issues of clinical relevance arise, in addition to considerations of replication in the clinic setting.

The choice of primary outcome is critically linked to the estimation of sample size, this being determined by the incidence of the outcome in the control group, as well as the difference between treatment groups that is anticipated being detected. As a general rule, the greater the incidence of the outcome and the greater the difference anticipated between the intervention and control group, the smaller the sample size required. In contrast, serious but rare clinical outcomes and more modest treatment effects require much larger sample size. Therefore, the choice of primary outcome often represents a compromise between what might be ideal and what is achievable. With declining maternal and perinatal mortality, researchers have focused on surrogate clinical endpoints and composite outcomes reflecting morbidity, both of which usually occur more frequently. The effect is to reduce a potential sample size of tens of thousands of women and their infants, to a smaller sample size that is more feasible and achievable. While this may represent a practical issue in the design and conduct of randomised trials, it may pose difficulties in the clinical interpretation, particularly where components of the composite outcome may vary in both severity and the direction of effect.[8,9] Furthermore, the choice of a surrogate outcome, which often represents a short-term measure, should correlate with and accurately predict the long-term or more serious outcome of interest.

Statistical analysis of randomised trials follows intention to treat principles, where participants are analysed in the group to which they were allocated. Analysis in this way ensures the effects of randomisation are maintained, the distribution of both known and unknown factors that may influence treatment outcomes being randomly allocated across treatment groups. In contrast, statistical analysis according to the actual intervention received essentially removes the effects of randomisation, introducing bias. From a trial design perspective, the challenge lies in ensuring that the process of randomisation occurs as close to the point of intervention delivery, maximising the chance that intervention is received as allocated.

It has been estimated that less than half of the one million trials conducted have been published[10], representing significant publication bias, with trials demonstrating positive treatment effects more likely to be published in English-language journals. In an attempt to reduce publication bias and selective reporting of trial results, prospective trial registration has been introduced, with an increasing number of journals requiring demonstration of prospective clinical trial registration prior to recruitment of the first participant.

The concept of a single randomised trial providing 'the answer' to a clinical question is somewhat of a fallacy, with most research raising and generating more questions than are answered. It has been stated that: 'Evidence does not speak for itself – it requires interpretation in light of its original context (and) limitations… in order to inform the practical decisions of other (clinicians).'[11] In view of this, clinicians require training to be 'sceptical and discriminating', to develop the skills required to make the best use of research evidence, and then generate positive changes in clinical practice to improve health outcomes.[12]

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Publication bias

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The practice of the selective publication of manuscripts that demonstrate positive results or seemingly favourable outcomes is known as publication bias.

The phenomenon of publication bias typically arises from one or both of two sources: the investigators or the publishing medical journal. The failure of investigators to submit 'negative' outcomes to journals for consideration of publication is the most common source of publication bias.[1] The researchers whose study shows a non-significant or negative result may be reluctant to submit their manuscript to a journal, as they often consider the chance of acceptance for publication to be low. Additionally, some journals may be less inclined to publish submissions with non-significant results.

> 'The publication of outcomes of medical studies in peer-reviewed journals is central to the foundations of effective healthcare.'

The problems with publication bias

Why should we be concerned about selective publication practices? Fundamentally, the problem with selective publication of favourable results is that over time it will produce distortion of the medical literature by creating excessively positive outcomes for interventions and the potential for overestimation of treatment effects. The absence of negative or inconclusive trial results will produce significant bias in the medical literature towards interventions and treatments.[2] Thus, as a consequence of publication bias, inappropriate patient management decisions could be made by healthcare providers. This is an important issue given the emphasis on clinical decision-making and care protocols on the results of meta-analyses and systematic reviews, where overall treatment effects are calculated on published results. The capacity of systematic reviews to detect moderate but clinically important treatment effects may be adversely affected by publication bias. It has been reported that publication bias may be present at some level in 50 per cent of meta-analyses and strongly in up to 20 per cent.[3]

Previous reviews have documented the inequality between the number of studies approved by Institutional Ethics Committees and those that are actually published (publication deficit). While some of this discrepancy may be secondary to methodology problems and study conduct issues, there is evidence to suggest the chances of publication are higher with a significant study outcome.[4,5] In a review of 649 approved studies, those with a significant result were more likely to be published than those with a non-significant result (OR 4.6, 95 per cent CI 2.2,9.5).[5] In addition, those with significant results were published in a shorter period of time (OR 2.5, 95 per cent CI 1.4,4.6).[5] In fairness, not all publications have consistently reported these trends: in a review of abstracts presented at six consecutive European Society of Human Reproduction and Embryology (ESHRE) annual meetings, Evers reported that 56 per cent of randomised controlled trials were eventually published and that this publication rate was not influenced by significant results.[6]

Medical journals and publication bias

The concept of publication bias and medical journals extends beyond just the potential for selective selection of manuscripts published. There are other ways in which a medical journal can, often quite insidiously, engage in publication bias, for example:

- selection of specific reviewers for the submission;
- choice of a supporting editorial in the same issue;
- organisation of press releases or press conferences; or
- preferential publication of manuscripts from English-speaking nations.

For healthcare providers wishing to have available the most appropriate information for their patients, it is important that the data available are comprehensive and unrestricted. The publication of outcomes of medical studies in peer-reviewed journals is central to the foundations of effective healthcare. The failure to report study results by investigators just because they do not show a positive result is scientifically unethical. This responsibility must over-ride commercial interests such as fiscal sponsorship from external commercial funding sources.

Medical journals have a duty to publish in a neutral and scientifically correct manner research that is appropriately conducted and methodologically sound, regardless of the study outcome. The care with which medical journals perform the task of manuscript selection is central to non-biased data publication. Journals should be wary of losing their academic rigour in an attempt to be fashionable and to maintain a scientifically appropriate relationship with the media that does not compromise the basic tenet of a medical journal.

Methods to reduce publication bias

Recognising the potential concerns and inequities of knowledge dissemination that may occur from selective publication of trials, the question arises: what can we do about it?

There have been some important strategies over the past decade to reduce some aspects of publication bias. In 2004, the International Committee of Medical Journal Editors (ICMJE) developed a policy of mandatory registration requirements for new and ongoing clinical trials as a requirement for publication. The aim of this was to permit greater transparency in research and reduce the chance of trials not being recognised. There are now several trial registries approved by the ICMJE – including the Australian Clinical Trials Registry (http://www.actr.org.au) – and each approved trial registry

must meet a minimum data registration requirement developed by the World Health Organisation (http://www.who.int/ictrp/network/trds/en/index.html). To overcome the potential for multiple trial registries operating simultaneously but non-cohesively, WHO has created an international system of linked registries and interested readers should access the WHO International Clinical Trials Registry Platform for detailed information on the process of clinical trials registration. In keeping with the aforementioned philosophy of ICMJE and WHO for consideration of journal publication, the *Australian and New Zealand Journal of Obstetrics and Gynaecology* (*ANZJOG*) now requires all trials that prospectively recruit human subjects to any intervention to be registered with a clinical trials registry.

Of course, mandating registration of clinical trials as a requirement for journal publication will not eradicate publication bias on its own. It is a fundamental research principle that studies are designed with adequate power to provide a definitive answer, with methodology that is correct to address the research question and are not commenced when the chance of completion is low. It is vital that researchers submit completed studies to journals and do not perceive a non-significant finding as a failure. Similarly, it is important that journals should publish studies that are appropriately conducted and analysed, regardless of the statistical significance of the findings. It is plausible that many researchers fail to write or submit manuscripts when the outcomes are non-significant and that there is a tendency for such publications, when submitted, to be accepted in journals of a lower impact factor.

Conclusion

Publication bias in medical journals has the potential to adversely affect patient care by the preferential publication of positive studies to produce an unrepresentative impression of the total research data available. It is important that researchers employ scientific rigour to design and conduct research appropriately and medical journals review and publish manuscripts on their scientific merits, not their p value.

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Transvaginal mesh

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How should we interpret the evidence available for the use of transvaginal mesh in prolapse surgery?

About 20 years ago, many gynaecologists began to express disquiet about the long-term success of the conventional vaginal procedures performed for pelvic organ prolapse (POP), particularly for the long-term cure of cystocele. As dissatisfaction took hold towards the end of the 1990s, publications appeared that seemed to confirm what now seems set as a dogmatic assertion: all conventional vaginal surgeries for the correction of prolapse have unacceptably high failure rates.

At the same time, evidence from general surgery began to accumulate, indicating that hernia repairs could be made more durable by using artificial polypropylene mesh. That observation stimulated a new insight in gynaecologists: maybe a prolapse was just like a hernia. By this time, the evidence appeared overwhelming that new procedures were required to replace the seemingly dated and unsatisfactory vaginal repairs – and the key to increased durability would be polypropylene mesh.

Initially different types of mesh were used, some good, some bad and some decidedly ugly. Accumulated experience with mesh revealed that lightweight monofilament polypropylene was superior to dense multi-filamentous materials, which tended to become encapsulated and not incorporated, thereby producing troublesome inflammatory reactions and rejection. Industry has been ingenious in the manufacture of new products and, today, there is a bewildering array of products to choose from.

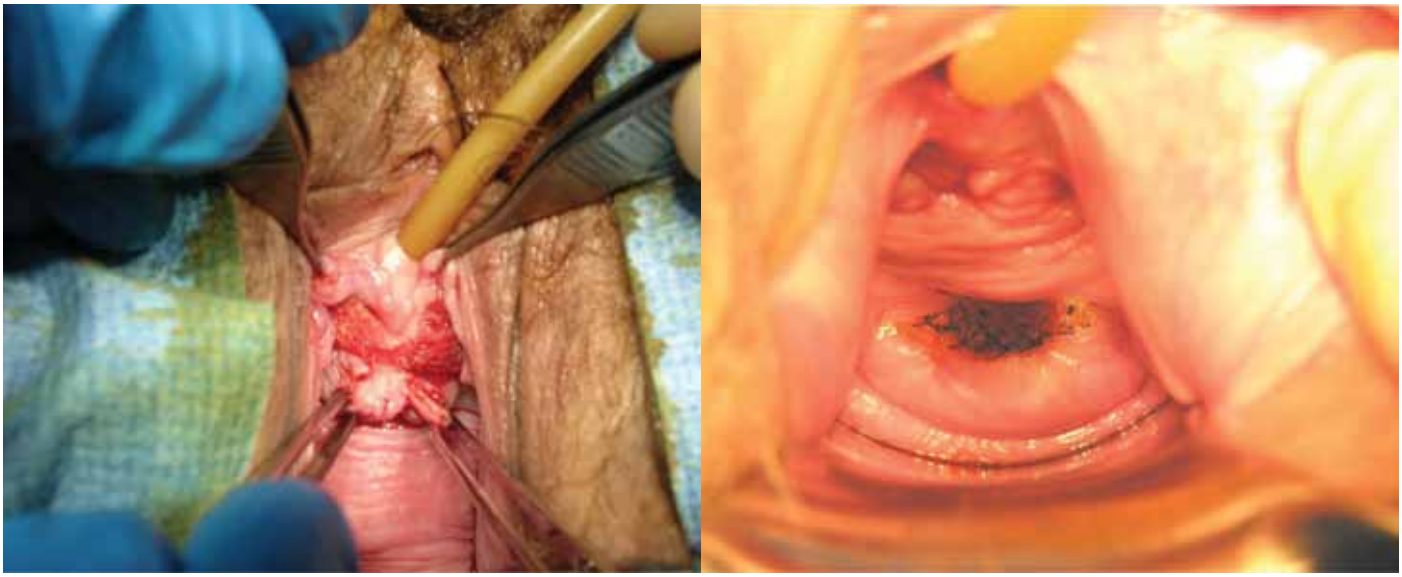
Recently, however, dissenting 'anti-mesh' voices have become increasingly strident. Awareness has developed of some unique and potentially enduring complications associated with the use of vaginal mesh and authorities are re-evaluating the issues. Generalist gynaecologists watching these arguments develop would be forgiven if they were to cry despairingly, 'A pox on both your houses!' But, as a lesser poet than Shakespeare, Oscar Wilde, observed, 'The truth is rarely pure and never simple.'

Some literature revisited

You may be familiar with the mantra that, '29 per cent of operations for vaginal prolapse fail and require further surgery.' This figure comes from an article written by Ambre Olsen and her colleagues, published in 1997.[1] This single article seems to be cited more often than any other in the world literature, or so it seems to me. This level of citation of a single 15-year-old publication must be remarkable. In all cases the Olsen article is used to illustrate the poor outcome of surgery for POP, quoting a reoperation rate of 29.2 per cent. I began to wonder about this figure and, a couple of years ago, decided to do something remarkable – I actually went back and read the paper!

The publication is a retrospective case note analysis of surgery performed for POP and/or urinary incontinence (UI) in the north west of the USA in a single year, 1995. They identified 384 cases where surgery had been performed for either POP or UI (and sometimes both). In 112 cases (29.2 per cent) this surgery occurred in someone who had a previous procedure for either POP or UI. Although this statistic is the origin of the oft-quoted reoperation figure, it is actually not possible to determine whether the reoperation was for UI or POP. And, if it was for POP, it is not possible to say whether they were same site recurrences or a different site.

In subsequent interpretations, an assumption is made that if an anterior repair was performed it was for prolapse, but the authors clearly state that it may just as well have been for UI. In 212



Exposure of the mesh through the vaginal wall can be a troublesome complication to manage.

cases the surgery was definitely for UI, since the procedures were either retropubic suspensions or needle suspensions. Thus, an indeterminate number of re-operations may have been undertaken for recurrent incontinence rather than recurrent prolapse. Why doesn't anyone cite this article as an illustration of the failure rates of procedures for UI?

The mean period from original surgery to the first repeat operation was 12.5 years, meaning that many of the repeat procedures were being performed in 1995 on women who had had their first operation in the early 1980s. A good deal changed in those years. I commenced my gynaecological training in the early 1980s and, by 1995, I did almost nothing the way I was originally taught.

I suspect that many subsequent authors who quote the Olsen citations have not read the original article carefully. The high reoperation rate fits perfectly with the prejudice that traditional vaginal surgery is lacking any long-term effectiveness and, perhaps, is even obsolete. These perceptions have driven the laparoscopic approach and the use of vaginal mesh. I am not suggesting for one second that conventional prolapse procedures do not have a failure rate, simply that it may be time to be a little more sophisticated about what is actually meant by 'recurrence' and 'failure'. Many anatomical 'recurrences' may not even be symptomatic. In large population-based studies, some 20 per cent of older women have been found to have an asymptomatic POPQ grade two prolapse of one or other vaginal compartment.

The fundamental issue lies in the definition of 'cure' for prolapse. Unlike surgery for stress incontinence, outcome measures for prolapse surgery are poorly standardised. Most early studies relied upon anatomical descriptions: does an examining doctor think there is, or is not, a prolapse? More recently, subjective outcomes have been described: what does the woman feel is the outcome? On this basis, there is a clear discrepancy between what the woman says and what the examining doctor sees – there is a much lower 'failure rate' when we listen to the woman. If an endpoint, such as same-site reoperation rates, is measured, it gives a 'failure rate' of between five and ten per cent at one to five years after a conventional primary repair.[2-4] This sounds a bit better than 29 per cent, doesn't it?

The problem of surgical morbidity

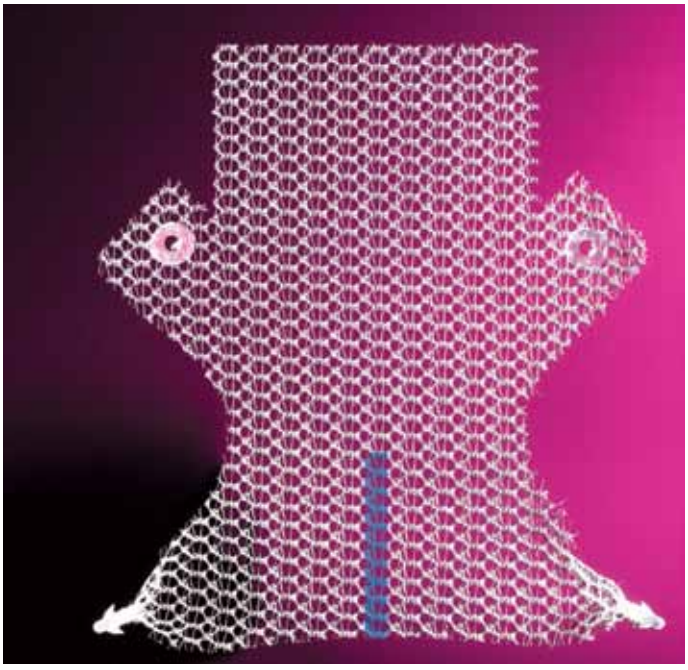
Say a new prolapse procedure is performed on 100 women and, postoperatively, five women are unable to have intercourse because of pain, but ten other women are able to recommence satisfactory intercourse now that they have no prolapse. So, more women are sexually active after the procedure than before. Is that a 'good' operation? Certainly not according to the five women with dyspareunia!

This introduces yet another variable: the perceived complexity, or simplicity, of the procedure we want to perform. This is an important concept in prolapse surgery. A conventional repair is considered technically straightforward, a mesh repair more challenging and an abdominal sacrocolpopexy perhaps most challenging. They all have different morbidity risks and the magnitudes of those risks are different. If a simple and safe surgical method of treatment wasn't quite as 'good' at fixing the problem, how do we trade off the simplicity (and lack of patient morbidity) against the lesser effectiveness? What tools can be use to perform such a balancing act? How 'less effective' is it allowed to be before a technique is discredited and we say, 'it's not worth it'? Are there worse things following a pelvic floor repair than failure? And, if there are, exactly what are they?

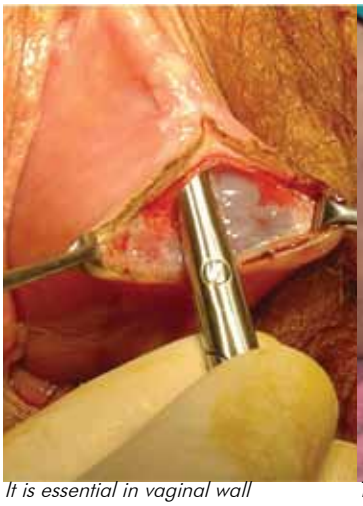
Even if the failure rate of conventional surgery is lower than previously suggested, what are we to suggest for those women who have recurrent prolapse? I would certainly miss the option of vaginal mesh in these cases.

Bad news from the FDA

Since the US Food and Drug Administration (FDA) report was released in 2011, many gynaecologists have become nervous about using transvaginal mesh in prolapse repairs. Perhaps this is not necessarily a bad thing. However, the FDA report created a strong impression that there had been an enormous number of serious unique complications reported with the use of vaginal mesh, and



A number of mesh solutions have been developed by industry. This is the anterior Elevate mesh from American Medical Systems.



It is essential in vaginal wall dissection to get beneath the mucosal fascia. This runs the risk of inadvertent cystotomy.

The clinical problem of severe prolapse poses major technical challenges; one of the suggested solutions is polypropylene mesh.

that these cases were just the tip of a looming iceberg. Using, what I consider to be, a selective reading of the literature, the FDA overtly declared there was no real evidence of the effectiveness of mesh when compared to more conventional surgical techniques. Recent figures suggest that as a consequence of this adverse report and concerns over litigation, the use of mesh in the USA has declined by 30–40 per cent. It should be placed on record that the Australian equivalent body, the TGA, has reported no similar increase in complaints about the use of vaginal mesh and the largest supplier of medico-legal services to our profession in Australia does not see vaginal mesh as a particular issue at this time.

The same FDA report lauded the effectiveness of mesh placed abdominally and suggested that the technique of abdominal sacrocolpopexy was the 'gold standard' of pelvic floor repair. *The Australian* newspaper quoted a gynaecologist talking about 'cheese grater' vaginas produced by mesh exposures, an alarmingly emotional response with no basis in fact and an unhelpful contribution to this important debate. So, what is the real situation?

The magnitude of the vaginal mesh 'problem'

The FDA estimated that, in the three years covered by the report, a total of 225 000 vaginal mesh procedures were performed. There were 1503 reports of adverse events in the three years, which yields a rate of complication of 0.67 per cent, a fairly modest figure. (There were also 1371 adverse events reported with suburethral slings, but for some reason this did not produce any furore.) Despite this, the report implies that on the basis of these figures that the rates of complications are higher than conventional repair. Does anyone seriously think the rate of complications in standard repairs is less than one per cent?

All surgery involves risk. Mesh complications are being reported. No one is reporting much adverse data on conventional repairs (apart from 'failures'). Quite simply, no one is looking.

Some assertions

1. Mesh used in pelvic floor surgery introduces risks not present in non-mesh surgery for POP repair.
   These risks are said to be mesh erosion, pain, infection, bleeding, dyspareunia, organ perforation and urinary problems. These risks exist, of course, but with the exception of mesh erosion they also exist with traditional surgery. Furthermore, the risk of mesh erosion also exists with abdominally placed mesh.
2. Mesh placed abdominally has lower rates of mesh erosion and has excellent durable success rates.
   The truth is that in reported series of vaginal and abdominal surgeries in experienced hands, erosion rates are actually pretty similar (3.3 per cent vaginal[5] versus 4.3 per cent abdominal[6]). Even if it was true that mesh exposure rates are lower, they are not zero. As well, the material the mesh is made from is identical in both procedures. It is clear that, given the highly variable reported rates of mesh exposure in both vaginal and abdominal mesh, differences in surgical techniques most likely underlie the differing rates of mesh erosion.
   However, mesh erosions are not the only complication we should be concerned with when comparing abdominal and vaginal approaches to POP surgery. Significant gastrointestinal morbidity after sacrocolpopexy occurs in 20 per cent of patients.[7] The difficulty in assessing success rates is partly due, again, to the vagaries of how 'success' is measured after sacrocolpopexy. If you use descent of point C (the vault) as an endpoint, it has to descend almost the entire total vaginal length before it is accounted a failure: whereas the other points on the vaginal walls only have to descend 1cm or 2cm before they reach the hymenal ring (point 0 on the POPQ) and 'fail'.
3. Mesh shrinkage produces intractable pelvic pain at rest and pain with intercourse, which is impossible to treat.
   Many of us have heard terrible stories of distress and pain following vaginal mesh repairs. However, the reporting of a whole series of alarming complications referred to your practice is not a valid investigative tool. There are now a reasonable number of studies looking at postoperative pain, adverse mesh events and sexual functioning following vaginal mesh repairs.

One of the best randomised studies was published in the *New England Journal of Medicine* in 2011 by Altman and colleagues, a large multicentre study with many of the centres in provincial Scandinavia.[5] It tells us much about what outcomes can be expected with the use of vaginal mesh in the widespread practice. This was a multicentre randomised trial of anterior Prolift™ mesh versus traditional anterior repair. Two hundred patients had the mesh and 189 had a standard repair and were followed up for one year. Multiple endpoints included quality of life (QoL) and sexual functioning. Cure of prolapse was defined anatomically and by a negative response to the question: 'do you feel any vaginal bulge sensation?' An intention to treat analysis was performed on those women who returned for follow up: 186 in the mesh and 182 in the traditional repair group.

> 'Australia has been, and remains, at the forefront of research into these surgical technologies with many innovations arising from our shores.'

The mesh group had superior cure rates at one year: 60.8 per cent in the mesh group versus 34.5 per cent in the conventional group. Mesh surgery took longer (52.6 mins versus 32.5 mins) and caused more blood loss (84.7ml versus 32.5ml). Severe pelvic pain at two months was reported in five mesh cases (2.7 per cent) and in one anterior repair, but by 12 months only one case in the mesh group still reported pain (0.53 per cent).

De novo stress leakage is more common after mesh repairs and, by one year, five patients in the mesh group had undergone sling surgery. There were six subsequent procedures for mesh exposure (3.2 per cent) by one year. All were cured. Pain on intercourse 'usually' was noted by 7.3 per cent of mesh group patients, and two per cent of the conventional repair patients. However, overall general satisfaction with sex was identical between the two groups (40 per cent). One patient underwent surgery for prolapse failure in the conventional group by one year.

So, which patients should consider mesh?

This is not an easy question to answer since clear evidence is lacking and no guidance can be given regarding which mesh kit should be used since there is simply no robust comparative data

available. A recent useful consensus statement has been published in the *International Urogynaecology Journal*[8] and a summary of the recommendations is shown in the table. Primary prolapse, patients younger than 50, lesser grades of prolapse and posterior compartment prolapse without apical descent are unlikely to benefit from mesh.

Evidence and risk

No surgical procedure is without risk. But what is an 'acceptable' risk and what is an 'unacceptable' risk? This is a critical topic and goes to the heart of this discussion. Everything comes at a price. In Australia, we can all strongly support the FDA recommendations for patients to engage in a dialogue with the treating surgeon regarding the use of mesh and be fully informed regarding the potential benefits and hazards of such surgery. But, where possible, the magnitude of these risks should be based upon data. While the data are not complete, it is mischievous to imply they do not exist.

Australia has been, and remains, at the forefront of research into these surgical technologies with many innovations arising from our shores. RANZCOG has the oldest formal training program in the world devoted to the management of POP, ensuring a well-informed and highly skilled workforce of subspecialists in this area for the last two decades. The incidence of complications when using artificial mesh in prolapse surgery is likely to be related to surgical expertise, training and work volume as well as the adequacy of the patient-selection process. The most important fact remains that surgeons who use mesh infrequently in improperly selected cases will get higher rates of complications. This is what the evidence tells us.

Declaration of interest

Malcolm Frazer holds contracts as a preceptor for Johnson & Johnson Gynecare as well as American Medical Systems mesh products for which he receives a fee. He has received financial support from both organisations to attend scientific conferences as an invited lecturer.

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Table 1. Potential benefits of polypropylene mesh use for vaginal prolapse (adapted from[8]).

Variable		Likely benefit	Possible benefit	Unlikely benefit	Not recommended
Age					
	Less than 50			✓	
	More than 50		✓		
Recurrent same site			✓		
Cystocele					
	Less than grade 2			✓	
	More than grade 2		✓		
Rectocele				✓	
Apex			✓		
Deficient fascia			✓		
Raised pressure			✓		
Pain syndromes					✓
Pregnancy					✓
Combination factors					
	Recurrent cystocele > 2	✓			
	Recurrent posterior		✓		
	Recurrent vault/cervix	✓			
	Recurrent + increased intra-abdominal pressure	✓			
	Recurrent + deficient fascia	✓			

GBS screening

Dr Nick Walker
FRANZCOG Trainee

Group B Streptococcus is a common commensal and a rare pathogen: what is the evidence for screening and treating pregnant women?

No article on streptococci can begin without mention of the incredible lifetime work of Dr Rebecca Lancefield (1895–1981). For 60 years, she categorised and published scientific papers on these occasionally pathogenic microbes, whose serotypes bear her name. Lancefield Group B Streptococcus, (GBS, also known as Streptococcus agalactiae), is a commensal organism of the rectum and lower genital tract in males and females. The most recent New Zealand prevalence data are from 2002, where GBS was detected in 22 per cent of women in Auckland and Wellington between 35 and 37 weeks gestation.[1] This is consistent with similar studies in Australia and worldwide.

Though GBS is far more frequently detected in expectant mothers than syphilis, Hepatitis B and HIV, the vertical disease transmission rate is far lower, with only 12 per 1000 newborns of colonised mothers developing early-onset GBS (EOGBS) disease[2], which is defined as infection occurring within seven days of birth. The majority – around 90 per cent – occur within 24 hours and are suspected to begin intrapartum by ascending colonisation into the amniotic fluid after membrane rupture. Though the attack rate is low, GBS is nevertheless the most frequent cause of severe early neonatal infection, with a mortality rate ranging between five and 20 per cent. It is thus an important problem.

The 1970s and 1980s

Knowledge of the existence of GBS as both a vaginal commensal and a neonatal pathogen led, inevitably, to the question of an intrapartum link, which was established in the 1970s with studies examining the serotypes which caused sepsis, meningitis and pneumonia in newborns. Epidemiologic studies showed that women colonised with GBS were 25 times more likely to deliver a baby with EOGBS than non-colonised controls. Additional risk factors were sought and elucidated in 1985: gestation <37 weeks, membrane rupture >12 hours, and/or intrapartum fever >37.5C are associated with a 6.5-fold increase in the risk of disease.[3] These parameters remain part of many current GBS management guidelines.

In 1979, Yow showed that vertical transmission of GBS could be interrupted with the administration of intrapartum ampicillin, resulting in 0/34 neonates being colonised with the bacteria, compared to colonisation of 14/24 untreated neonates.[4] Numerous repeat studies in the UK and Europe confirmed the finding. Then, in the 1986 landmark paper by Boyer and Gotoff, intrapartum chemoprophylaxis was found to reduce not only colonisation, but also found a zero per cent (treated) versus six per cent (untreated) rate of neonatal bacteraemia.[5] Having demonstrated that the risk of EOGBS could be reduced by intrapartum chemoprophylaxis, the next question was whether this could be applied to the general antenatal population.

The 1990s

Understanding that penicillin and ampicillin could reduce the rate of EOGBS, researchers continued to search for strategies to best detect and manage GBS colonised antenatal patients and/or newborns likely to develop EOGBS. At this point two options predominated in clinical practice:

1. GBS culture-based screening; and
2. risk-factor-based screening.

GBS culture-based screening has the following evidence basis:

- Studies have determined that for optimal detection of GBS, swabs should be collected from the lower vagina and rectum (same swab or separate swabs, clinician- or patient-collect).
- Specific microbiological techniques are used to culture and identify GBS, thus laboratory request forms must state the need for GBS culture. In patients with a penicillin allergy, sensitivity patterns must also be requested, as there is 15–30 per cent resistance to clindamycin and erythromycin, which are the main alternatives for prophylaxis in these patients.
- Because colonisation is transient within and between pregnancies, screening is required for each pregnancy.[6] Gestation for GBS screening is ideally within five weeks of delivery. In practice this is 35–37 weeks.[7]

Risk-factor based screening has the following evidence basis:

- Besides known GBS colonisation, maternal risk factors for delivering a neonate at risk of EOGBS have been elucidated and repeatedly confirmed by many observational studies[8-11], and generally include gestation <37 weeks, membrane rupture >18hrs, intrapartum fever >37.5C, and low levels of maternal GBS capsular antibodies.

The method of treatment for screen-positive pregnant women has a strong evidence base. Studies confirm that both penicillin and ampicillin reduce neonatal colonisation and infection from GBS, with some effect seen when administered at least two hours before delivery, but a more certain effect if given at least four hours before delivery. As time of delivery is not usually able to be predicted accurately, four-hourly dosing is recommended.[12] The principle of treatment is to achieve therapeutic concentrations of antibiotic in the amniotic fluid and fetal tissues. Observational studies have shown this form of chemoprophylaxis to be nearly 90 per cent effective in preventing EOGBS.

There are two groups of patients who are exempt from screening, because risk factors independent of rectovaginal swab results make chemoprohylaxis mandatory. The first group is patients found to have GBS bacteruria during pregnancy. This has been shown to be a surrogate marker for heavy colonisation and, despite antibiotic eradication from the bladder, rectal/vaginal persistence is typical. The second group is patients who have had a previous neonate affected by EOGBS, which is thought to be due to reduced levels of maternal GBS capsular antibodies, which cross the placenta and are protective to the neonate.

Year 2000 and beyond

With both culture and risk-factor screening practices in place throughout the USA, a large multistate retrospective cohort study was published in 2002 to elucidate which of the two approaches was preferable.[13] The results were conclusive. Patients who had undergone culture-based screening had less than half the risk of having a baby with EOGBS than patients who had had risk-factor-based screening (relative risk 0.46). This finding informed policies and guidelines on the prevention of EOGBS published by both the American Congress of Obstetricians and Gynecologists (ACOG) and Centers for Disease Control (CDC) later that year, which recommend culture-based screening.

Informing current practice

Where does that leave today's practitioner? It appears to be dependent upon one's geographic location. Despite aforementioned arguments favouring culture-based screening, the Royal College of Gynaecologists and Obstetricians (RCOG) notes that there is no RCT evidence comparing the two screening methods, either with each other or with no screening, in their efficacy at preventing EOGBS.[14] The potential harms of false-negative swabs, penicillin anaphylaxis and antibiotic resistance are acknowledged. The RCOG has also noted that the UK rate of EOGBS (0.5/1000) is the same as that in the USA, without a structured and widely adhered-to screening policy. Another RCOG report on GBS[15] has found variation in international practice: of 14 guidelines: seven recommend culture-based screening, four recommend risk-factor screening, one suggested a combination approach (GBS culture collected, but only treated with prophylaxis if and when risk-factors develop) and one gave no preference. The current RANZCOG statement outlines both options, but gives no preference. Within New Zealand, across a range of units, guidelines suggest intrapartum prophylaxis for risk-factor positive patients, and an acknowledgement that late third-trimester swabs can be used to screen also, with a view to treatment if found to be positive for GBS.

In considering whether RANZCOG should produce a statement recommending culture-based screening for GBS, it may be worth revisiting the WHO guide for attributes of a successful screening test:

1. The condition should be an important health problem. Yes: the leading cause of severe neonatal sepsis with a significant mortality rate.
2. There should be a treatment for the condition. Yes: penicillin is at least 80 per cent effective.
3. Facilities for diagnosis and treatment should be available. Yes: a microbiology lab and access to penicillin.
4. There should be a latent stage of the disease. Yes: asymptomatic colonisation of the vagina before neonatal exposure.
5. There should be a test or examination for the condition. Yes: the collection of swabs and microbiological techniques are well established.
6. The test should be acceptable to the population. Yes: studies have shown high levels of patient acceptability, whether clinician- or patient-collected specimens.
7. The natural history of the disease should be adequately understood. Yes: intrapartum transmission leads to neonatal colonisation and/or infection.
8. There should be an agreed policy on who to treat. Yes: screen-positive individuals.
9. The total cost of finding a case should be economically balanced in relation to medical expenditure as a whole. This requires further consideration and study due to the low attack rate and large numbers of screen-positive individuals requiring treatment to prevent cases.
10. Case-finding should be a continuous process, not just a 'once and for all' project. Yes: there is an established body of work regarding the timing of swabs and the need to repeat the test each pregnancy.

Individual countries need to base their guidelines on the resources available. At present, in Australasia, both risk-based and culture-based screening approaches are employed by individual practitioners within the same unit, depending on the individual's response to the College statement. A RANZCOG statement that endorses a single preferred screening approach would certainly help to achieve uniformity of practice. Unfortunately, definitive evidence to back one approach over the other is lacking.

Acknowledgement

I would like to thank Dr Martin Sowter for his assistance with this article.

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Hormone therapy

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Hormone therapy is the most effective treatment available for the symptoms of menopause. Although a number of clinical trials have shown that it is not without significant drawbacks, substantially increased risks with short duration of use are unlikely for healthy women in early menopause.

Most women experience menopause between 40 and 58 years of age. Apart from cessation of periods, the commonest symptoms are hot flushes, night sweats, vaginal dryness and sleep disturbance. Hormone therapy (HT) is the most effective treatment for symptoms and a Cochrane review of randomised trials showed a 75 per cent reduction in flushes (18 fewer per week) with hormones compared with a 50 per cent reduction with placebo.[1]

Long-term HT for peri- and postmenopausal women

A Cochrane review looked at multiple outcomes and followed the usual Cochrane methodology.[2] It included 23 randomised double-blind trials of hormone therapy. Nearly all the statistically significant findings came from the two biggest studies, The Heart and Estrogen/progestin Replacement Study (HERS) and the Women's Health Initiative study (WHI).

Death from lung cancer

This outcome came mainly from the post-hoc analysis of the combined arm of WHI. After a mean follow-up of eight years, including 2.4 years' follow-up post-intervention when women had stopped taking hormones, women in the intervention group were significantly more likely to die of non small cell lung cancer (RR 1.91:CI 1.24 - 2.95) than women in the placebo arm. This is thought to be due to stimulation of the growth of pre-existing cancers. The finding was independent of smoking status and was not found in the oestrogen-only arm of WHI.

Death from breast cancer

No statistically significant difference was found between HT and placebo for this outcome at 5.6 years. When combined hormones were stopped and after a total of 11 years of follow up there were more deaths from breast cancer in the HT group than in the placebo group. This was of borderline statistical significance (RR 1.98: CI 1.00 -3.95).

Overall mortality

Also at this time, after 11 years of follow up, there was significantly more deaths from all causes occurring after a breast cancer diagnosis in the combined HT group than in the placebo group (HR 1.57: CI 1.01 -2.48).

Myocardial infarction

Pooled data from three studies showed an increased risk of myocardial infarction at one year (RR 1.89: CI 1.15-3.10) and at three years of use (RR1.45: CI 1.07 - 1.98) for combined HT. No other trials found any difference and at five years of use; the WHI study found no difference between groups. There was no increase with oestrogen only.

Stroke and transient ischaemic attack

Pooled data from two studies showed an increased risk of ischaemic stroke at three years with combined HT over placebo (RR 1.46: CI 1.02-2.09). At seven years follow up, the oestrogen-only arm of WHI also showed an increased risk of ischaemic stroke (RR1.35: CI 1.08 - 1.70) that became apparent after four years of use. No studies showed any increase in risk for transient ischaemic attack.

Venous thrombo-embolism

An increased risk of venous thrombo-embolism with oestrogen-only HT was found in pooled data from two studies with a statistically significant increase in risk at one year (RR 4.28). WHI data also showed an increased risk for oestrogen alone over placebo with a RR 2.22 at two years (CI 1.12 - 4.39) and this diminished with time so that at the end of the seven-year study the risk was RR1.32 (CI 1.00-1.74). In the combined HT arm of WHI, women taking hormones were also at a significantly higher risk of a thrombo-embolic event than women taking placebo at one year: RR 3.59 (CI 1.95 - 6.61) and at two years: RR 2.98 (CI 1.88 - 4.71) with the risk again diminishing over time.

Breast cancer

The oestrogen-only arm of WHI found a decrease in breast cancer with hormone use. This decrease became statistically significant when pooled with the data from the Women's International Study of long Duration Oestrogen after Menopause (WISDOM) study.[3] For the WHI study this non-significant trend for lower breast cancer rates in the HT group continued in the extended follow-up period and the overall cumulative breast cancer incidence over the entire 10.7 years of follow up showed a significantly lower rate in the HT group (RR 0.78:CI 0.63 -0.96). The decreased risk was for early stage disease and ductal carcinoma.

Subgroup analysis showed that the reduction in breast cancer was statistically significant only for those women who had no prior hormone use before study entry and only applied to women who had started oestrogen more than five years after menopause. For those women who had started at the time of menopause there was no advantage. This so-called gap time concept, the time from menopause to first use of hormones, remains controversial. Unlike the gap time hypothesis of potential decrease in cardiovascular disease if oestrogen is started early, the possible decrease in breast cancer may only be if oestrogen is started late.[4]

An increase in breast cancer diagnosis was found in the WHI study after taking combined HT for five or more years (RR 1.26:CI 1.02 to 1.56). For combined HT, breast cancer rates were initially lower; the suggestion being that combined HT may stimulate breast cancer growth, but delay diagnosis possibly by hindering mammographic detection. Subgroup analysis showed that women who had previously used combined HT, before joining WHI, had an increase in risk earlier, after three years of hormone study use.

Although the breast cancer risk decreased after hormones were stopped, the rate of invasive breast cancer was still significantly higher in the combined HT arm at a mean of 11 years of follow up (RR 1.25:CI 1.08 - 1.45). Breast cancers diagnosed in the HT group were of similar histology and stage to those in controls, but more likely to be node positive.

Endometrial cancer
No study showed an increase in risk of endometrial cancer with combined HT. Endometrial cancer is a well-documented adverse effect of unopposed oestrogen and in studies where oestrogen-only HT was used in women with a uterus, close monitoring showed that they were more likely to develop atypical endometrial hyperplasia.

Ovarian cancer
Ovarian cancer incidence was reported only in the combined HT arm, with no statistically significant difference over placebo after 5.6 mean years of use. However, a systematic review of mainly observational studies suggests that both long-term use of oestrogen-only and combined therapy may be associated with an increased risk of ovarian cancer.

Gallbladder disease
Three studies comparing oestrogen-only HT with placebo for the outcome of gallbladder disease requiring surgery showed a statistically significant increase in risk in the HT group (RR1.75:CI 1.40 -2.19). Four studies comparing combined continuous HT with placebo also showed significantly increased risk in the HT group (RR 1.55: CI 1.29 -1.86).

Cognitive function
Results for cognitive outcomes come from the WHI studies. In the Women's Health Initiative Memory Study (WHIMS), neither combined HT nor oestrogen only conferred any benefit in global cognitive function for women over the age of 65. The short-duration Women's Health Initiative Study of Cognitive Aging (WHISCA) study found, for all participants, a rise in mean scores used to measure global cognitive function, attributed to the learning effect of repeated administration of cognitive tests. However, a marked decrease in these scores occurred more frequently in the hormone treatment group, reaching statistical significance for combined HT.

Similarly, for the outcome of probable dementia there was a negative trend in both active treatment groups which reached statistical significance in the combined HT group. Evidence of increased risk in this group began to appear as early as one year after randomisation and persisted over five years of follow up. The overall risk of dementia in women taking combined HT was twice that of women in the corresponding placebo group. The investigators noted however that the absolute risk of dementia remained relatively small, at 45 per 10 000 postmenopausal women aged over 65 years who took combined HT for one year.

These findings were in contrast to earlier observational research and the investigators suggested that this might be due to the healthy user bias in observational studies; though it remains possible that there may be a critical period, such as menopause, during which HT needs to be initiated in order to protect cognitive function at a later age. However, previous users of HT in WHI, who had started hormones at a younger age, did not have higher scores.

Quality of life
There was no clinically meaningful quality-of-life benefit found in WHI, though these findings may not be applicable to women taking HT specifically for severe hot flushes that affect their quality of life.

At one year in the oestrogen-only arm of WHI there was a slightly greater improvement in sleep disturbance over the placebo group, which was statistically significant. However, the mean benefit – 0.4 points on a 20 point scale – may not be clinically significant. Moreover, a subgroup of women who were measured at three years reported no statistically significant benefit for any quality-of-life-related outcomes.

At one year, in the combined arm of WHI there was a difference in quality of life change scores for two out of eight categories in the RAND 36 survey: these two categories were improvement in physical functioning and decrease in role limitations owing to physical problems. However, these were not apparent during follow up at three years.

Fracture
WHI found a decreased risk of hip fracture for both oestrogen alone (RR 0.64: CI 0.45 to 0.93) and combined HT (RR 0.68: CI 0.48 to 0.97).This reduction became statistically significant only after five years of use. WHI also showed a decreased risk of vertebral fracture in both arms of the study, again after five years of use. In WHI, reduction in fracture risk with HT was no greater for women who had a higher risk of fracture.

Colorectal cancer
The combined HT arm of WHI also found a reduced risk of colorectal cancer compared to placebo after five years of use, which was offset by the finding that the cancers tended to be more advanced and with greater likelihood of lymphatic or metastatic involvement.

Health benefits and risks after stopping HT
The combined HT arm of WHI reported health outcomes at a mean of 2.4 years' extended follow up after the hormones were stopped. Over the course of follow up, the risk of coronary events, stroke and venous thromboembolism decreased in the group that had been randomised to combined HT and reached a level comparable with the placebo group. Similarly, the benefit for fracture and colorectal cancer had disappeared. As discussed previously, there was an increase in non clear cell lung cancer and some continued excess of breast cancer risk.

The oestrogen-only arm reported health outcomes at a mean of 3.9 years' extended follow-up after hormones were stopped. The increases in risk of stroke and venous thromboembolism rapidly disappeared as did the reduced risk of hip fracture in this group. As noted above, the lower incidence of breast cancer persisted and became statistically significant with extended follow-up to 10.7 years. WHI was not powered for sub-group analysis in the 50–59 year age group, but owing to the extended follow-up period the lower hazard ratios for myocardial infarction and coronary heart disease became statistically significant as did the lower breast cancer risk. The authors point out that an important caveat is that study participants

took unopposed oestrogen for a median duration of less than six years and that the results cannot be extrapolated to longer or shorter treatment durations.

Conclusion

Current recommendations favour the use of low-dose HT for relief of vasomotor symptoms taken for the shortest possible time required to achieve treatment goals.[5] Not all countries have low-dose packaged combinations and, for women with a uterus, individual prescribing of oestrogen and progestogen may be needed.[6] Individualised risk assessment will determine those women with high background risk of disease.[7] The primary aim of the WHI study was to see if the use of HT decreased heart disease and it was not designed or powered to determine the risks of use for symptoms in early menopause. However, subgroup analysis in the 50–59 year age group, showed only a small number of adverse events with combined HT. Healthy women have a low absolute risk of adverse events, whether they use short-term hormone treatment during early menopause or not. For women in their 50s without a uterus, taking oestrogen-only HT for five to six years appears relatively safe and there may even be some health benefits, however safety over a longer term use is unknown.

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Hysterectomy

Which approach, vaginal or abdominal, is best and on what evidence?

Dr Robert O'Shea
FRANZCOG
Head of Unit
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Dr Claire Francis
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Although hysterectomy remains a signature procedure in gynaecology, our approach has been in a state of flux over the past ten years. Analysis of Medicare data for hysterectomy for non-malignant indications shows that the total number of such procedures has fallen 20 per cent in the past ten years (2001–2011). Relative abdominal hysterectomy rates have reduced from 49 per cent (2001) to 34 per cent (2011). Hysterectomy via the vaginal approach has remained constant at 35 per cent (2001–2011). However, the rates of hysterectomy with some laparoscopic component has risen from 16 per cent (2001) to 31 per cent (2011). It would appear we are evolving, albeit slowly, from the abdominal to the laparoscopic approach for hysterectomy. Unfortunately, relative hysterectomy rates in the public sector are not universally available. We, however, have no reason to believe the statistics for the private sector have not been duplicated in our public-health system.

What is the evidence to support our various approaches to this procedure? The widely held view in gynaecology supports vaginal hysterectomy (VH), over an abdominal hysterectomy (AH), where feasible for non-malignant conditions. A recent Cochrane review[1] has favoured VH over AH, citing reduced infective morbidity and earlier return to normal activity. These findings have been broadly supported in the literature over a number of years. In comparing VH to LH, Cochrane[1] indicated that LH procedures were slower and resulted in increased blood loss. VH is undoubtedly currently regarded as the approach of choice for non malignant indications[1,2] where possible. When VH is not feasible, then AH or LH may come into play.

Following the introduction of laparoscopic hysterectomy in 1988, by Harry Reich, many gynaecological procedures are now almost universally performed via the laparoscopic approach. With two traditional approaches to hysterectomy (AH and VH), the field of options became increasingly crowded with the introduction of the laparoscope. Many believe that VH rates would rise dramatically over this period with falling AH rates. However, it would appear this has not occurred with the rates remaining relatively stable in Australia for VH at 35 per cent. The drop in AH rates has been taken up by the laparoscopic option.

Although the Medicare data show a 31 per cent incidence of laparoscopic assistance in hysterectomy, we are unable to clearly ascertain which procedures were performed, specifically laparoscopically assisted vaginal hysterectomy (LAVH), or total laparoscopic hysterectomy (TLH). With the introduction of the laparoscope into hysterectomy, LAVH was widely practiced in the 1990s. However, devotees of this approach have refined the technique to performance of their procedure totally laparoscopically (TLH). This technique allows improved visualisation, access to large uteri with no cervical descent required and facilitates concomitant procedures for other pelvic pathology, thereby covering a range of situations not accessible vaginally.

> 'As the Medicare data suggest, the numbers of hysterectomies performed in Australia appear to be reducing over time.'

As expertise in laparoscopic hysterectomy has evolved, comparison of TLH and VH has become possible.[3] Such recent randomised trials[4,5] have produced competing outcomes.

Gentry et al[6], performed a meta-analysis of five randomised controlled trials (RCTs), comparing TLH (n=332) and VH (n=331). No differences in blood loss, conversion to laparotomy or urinary tract injuries were noted. TLH was associated with reduced post-operative pain scores and reduced hospital stay, but took longer to perform. Higher urinary tract injury rates have been reported in laparoscopic hysterectomy, in particular ureteric injury and fistula formation.[7] Interestingly, this meta-analysis failed to find a difference between these groups, but did concede that the study was underpowered for such rare complications.

Currently, VH may be the preferred approach. However, what does the future hold? As the incidence of AH inevitably declines, how will the popularity of VH and LH fare. VH is currently taught by older, traditional gynaecologists. As time passes, will the younger breed of surgeons take up and teach this approach? It is very likely that abdominal hysterectomy will become relatively uncommon.

LH is currently being developed and taught by a number of endoscopic units throughout Australia. As such Fellowship programs undoubtedly spread; LH will increase its popularity, producing gynaecologists who will perform the bulk of the gynaecological surgery in the future. Although having sufficient gynaecologists trained in advanced laparoscopic surgery to supervise Fellowship programs may initially appear negative, new advances such as robotic surgery may shorten the current learning curve for LH and thereby increase its popularity.

As the Medicare data suggest, the numbers of hysterectomies performed in Australia appear to be reducing over time. This may well make it difficult for many gynaecologists to be both adequate laparoscopic and vaginal hysterectomists. It is more likely that the decision will be made to favour one or another in the majority of the cases.

There are a number of different considerations that govern which type of hysterectomy is performed. Training, confidence and competence are significant factors. Evidence-based medicine should be considered. In the future it is very likely that we will either evolve into predominantly laparoscopic or vaginal surgeons.

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Term Breech Trial

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The 'Term Breech Trial' and its aftermath is a prime example of how evidence itself can be put on trial.

Hannah and colleagues' so-called 'term breech trial' (TBT) was published over ten years ago now[1], and we still practise in its shadow. Many experienced clinicians urged caution in accepting the study's initial outcomes; data from the two-year follow-up of the babies was reassuring, revealing no significant differences in the major outcome measures with respect to death or neuro-developmental delay.[2] Time has told a different story, however, and the trend to deliver term singletons in the breech presentation by caesarean section has continued unabated.[3]

Why did we urge caution in accepting the TBT findings? Some clinicians and institutions who were originally approached to participate in the trial had expressed concern that the trial protocol was asking participants to undertake practices that were at the least unusual and, at best, not at all part of the routine approach to breech delivery in Australia and/or New Zealand at that time. I would summarise these issues as follows:

1. Although the breech delivery was to be 'planned', consent to enter the trial could be obtained while the woman was actually in labour, leaving little or no time for fetal assessment or maternal counselling.
2. Cardiotocographic (CTG) monitoring in labour was optional, even though the delivery was deemed 'high risk'.
3. The vaginal delivery (VD) rate for the breech delivery arm was to be more than 50 per cent even though that rate was achieved in only a very few selected specialist breech units in the developed world[4], and to achieve this oxytocin augmentation was to be utilised for delay in labour.
4. Included were women who had been delivered by caesarean section as well as babies with a weight of less than 2.5kg, even though this weight is associated with growth restriction at term.
5. Randomisation was to take place at or after 37 weeks, with the consequence that consequential numbers of fetuses would exceed the recommended upper range of weight of 4kg by the time labour commenced.
6. Fetal weight and attitude of the head (the degree of flexion), although considered important as entry criteria, could be assessed clinically if no ultrasound was available.
7. The degree of experience and training of the accoucheur appeared to be highly variable, including not only doctors with 20 years' experience, but also individuals who deemed themselves experienced, and who had their head of department attest to this, regardless of whether or not they had been observed as being competent.
8. The enrolment of women was to be ad hoc rather than consecutive. This left the potential for units to aim to deliver those women they thought highly likely to have a successful vaginal delivery and to randomise only the group in whom the prospect of a vaginal delivery was uncertain.
9. Units would not contribute equal numbers of caesarean and vaginal births (there was no blocking of the units by delivery). This had the consequence that one unit with an obstetrician highly competent in breech delivery could be made to deliver all the babies of women enrolled in the trial by caesarean section.
10. Units unable to provide emergency caesarean delivery within the hour were included. This also applied to units unable to provide oxygen to a baby for up to ten minutes after birth, and/or intubate a baby for up to 30 minutes.

It seemed apparent to many that the trial protocol was not necessarily optimal to answer the question as to whether: a mother with a singleton breech presentation at term in Australia or New Zealand, who has a complete pre-labour fetal and maternal assessment; has adequate and experienced counselling; can have continuous CTG monitoring in labour in a unit that can provide timely caesarean delivery and has neonatal resuscitation facilities; and can be attended by a well-trained, experienced and enthusiastic obstetrician, is better delivered vaginally or by planned caesarean section.

The investigators tried to account for the differences in facilities and standards by separating those centres with a perinatal mortality rate (PNMR) of less than 20/1000 births from those with a PNMR of more than 20/1000. A PNMR of less than 10/1000 is now common in units in the developed world and such units still differ markedly in their ability to mount a rapid caesarean and neonatal resuscitation response when compared to those with a PNMR of more than 10/1000.[5-7] Ultimately, this subanalysis by dividing the units participating in the TBT was probably meaningless.

Undertaking large clinical trials can be a little like politics – full of compromises and confessions. Everybody understands this. Given the trial as published, and the subsequent published data flowing from it, are we still justified in saying that the term breech trial indicates the superiority of planned caesarean section over trying for a vaginal delivery? Numerous publications have critiqued the TBT[3-7], and space constraint allows only a summary of the issues here:

1. The 121 centres entered 2088 women into the trial over 39 months. This amounts to five participants from each centre per year. This tiny number opens the trial to potential selection bias.
2. Despite being a 'planned breech trial', only 21.5 per cent underwent an attempt at external cephalic version (ECV). This would appear to be a rather low proportion, placing a question mark over the adequacy of counselling of the participants.[7]
3. How rigorous and robust was the inclusion process? Despite the TBT inclusion criteria of singleton, non-footling breech with flexed attitude, weighing less than 4kg, the trial reports enrolment of two dead babies, two sets of twins, and anencephalic and a spina bifida baby. In addition, 5.8 per cent of fetuses in the vaginal delivery group were over 4kg at birth, and in 4.1 per cent the type of breech was not recorded.
4. Of the women enrolled in the trial, 40 per cent entered with no ultrasound assessment of fetal weight or attitude of the head.
5. Of the 13 deaths attributed to the vaginal delivery group: two were 'most likely' dead before randomisation; two died after discharge (one attributed to sudden infant death syndrome and the other to gastroenteritis); two died because of respiratory difficulties after birth (calling into question the

adequacy of the neonatal resuscitation); one most likely had a congenital anomaly; and a further three had an abnormal fetal heart tracing, but do not appear to have been delivered by caesarean section in a timely manner. Only three died after what was described as a 'difficult delivery'. In his own analysis of the original data, Glezerman assumed that up to five deaths in the vaginal delivery arm could be attributed in some part to mode of delivery, as against two in the caesarean arm.[6] This made the delivery mode PNMR 5/1038 vs 2/1038, yielding a non-adjusted p value of 0.45: a non-significant difference.

6. Despite the undertaking that only a qualified person would attend the delivery, 6.7 per cent of the vaginal breech deliveries were delivered by people with little or no expertise as opposed to 2.7 per cent in the caesarean arm. Over 30 per cent of the morbidity/mortality in the group delivered vaginally was from this 6.7 per cent of deliveries. Kierse provides a complete reanalysis of morbidity data.[7]
7. The morbidity data is inconsistent. Fourteen babies in the caesarean arm were said to suffer severe morbidity, but 16 were admitted to a neonatal intensive care unit (NICU). Of more concern, eight of the 39 babies who had 'severe morbidity' in the vaginal delivery arm apparently were never admitted to a NICU.
8. A skull fracture was sustained during a caesarean birth and a death in the caesarean section arm occurred after the fetus was allowed to labour and deliver vaginally following augmentation with oxytocin. A further 27 per cent of the caesarean section group delivered vaginally after labour was augmented with oxytocin. Incidents and violations of protocol such as these are to be expected in any large, multicentre trial, but bring into question the abilities and commitment of trial participants.
9. Of the 69 cases of mortality and morbidity in the original trial, Glezerman could find only 16 that could be attributed to mode of delivery from the data as published. The vaginal delivery versus caesarean section perinatal morbidity rates were calculated as 11/1038 vs 5/1038, with a p value of 0.2, which is not statistically significant.[6]
10. Outcome data presented from the neonates was only short term. Long-term morbidity was not assessed in the original TBT paper.

Despite all these issues, the authors of the trial indicated that perinatal mortality, neonatal mortality or serious neonatal morbidity (as a composite outcome) was significantly lower in the planned caesarean section group compared to the planned vaginal delivery group (RR 0.33; 95 per cent CI 0.19-0.56: p < 0.0001).[1]

In a follow-up paper published in 2004 (a paper that obstetricians the world over have chosen to either dismiss or ignore[3]), data from the two-year follow up of infants delivered in the original TBT were presented.[2] A total of 923 of 1159 children (79.6 per cent) from 85 centres were followed to two years of age. The risk of death or neuro-developmental delay was no different for the planned cesarean than for the planned vaginal birth groups (14 children [3.1 per cent] vs 13 children [2.8 per cent]; RR 1.09; 95 per cent CI, 0.52- 2.30; P = 0.85; risk difference, +0.3 per cent; 95 per cent CI, -1.9 per cent, +2.4 per cent).[2] These outcomes suggest that the markers of severe morbidity used in the trial were ultimately not useful.

Further data published have looked at various risk factors in the vaginal delivery arm. Neonatal morbidity is more likely with the use of oxytocics, prolonged second stage and where the birth weight was less than 2.8kg.[8] That morbidity was less likely with an experienced clinician.[8] Such findings support the Royal College of Obstetricians and Gynaecologists (RCOG) breech delivery guidance.[9] The lowest absolute risk for the mother is by way of vaginal delivery. For those delivered by caesarean section the risk is highest if it is performed after labour has commenced (OR 3.33; 95 per cent CI:1.75-6.33, p <0.001).[10] It is worth remembering that caesarean delivery for breech may also result in maternal mortality.[5]

Many of us believe that we were subjected to vehement and at times intensely personal abuse because we dared to question the conduct and findings of the TBT. The final outcomes that were more reassuring are of little comfort. Breech delivery does carry a risk and should be carried out only after careful consideration and counselling.[9,11] The art of delivery has in some places been lost through the headlong dash of many obstetricians to the comfort of caesarean delivery and the exhortations of the vociferous randomised controlled trial lobby.

We have been told over the last ten years that the randomised control trial is the only form of trial to be undertaken, and for any other form of trial, 'we'd suggest you stop reading'.[5] Others would disagree with this. A trial is only as good as the relevance of the clinical question it seeks to answer and the parameters it uses to measure outcome. Complex clinical issues like breech do not lend themselves to controlled trials and inappropriate outcomes such as neonatal hypotonia lead to unjustified conclusions.[4]

To summarise, the TBT did not show any benefit for the fetus delivered by a planned caesarean section. Rather, it showed that caesarean section increased maternal morbidity.[2,10] Planned vaginal delivery, therefore, must become part of the armamentarium of the competent obstetrician. With regard to the trial itself, we should learn from the issues it raised. As Grant opined, 'the term breech trial is an example of a randomised trial that was impeccable as regards its methodological design, but questionable as regards its clinical design.'[12]

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Placebo effects

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What are placebo effects and what is their relevance? Mention of placebo may still evoke images of charlatanism in practice or of nuisance in research. This article seeks to resolve some confusion concerning this pervasive phenomenon in medicine. Regrettably, space does not allow discussion of recent neurobiological insights into mechanisms.

Responses to therapy have been attributed to three main processes:

1. Natural history (including regression to the mean), which recognises the self-limiting nature of some illnesses or random variations in illness expression. Measurement error may also contribute to such observations.
2. Specific effects attributable to the characteristic content of the intervention, such as a drug or a procedure.
3. The so-called 'nonspecific' effects of treatment, those that may be associated with the sociocultural context in which a treatment is delivered. These are referred to as placebo effects, but this concept requires further explication.

Placebos, placebo responses and placebo effects

A placebo is a substance or procedure that has no inherent power to produce an effect that is sought or expected. Placebos are used as a 'control' intervention in experimental trial situations; however, it is considered unethical to administer a known placebo in a clinical therapeutic situation (unless informed consent has been obtained). In the experimental case, placebos appear to have their own 'pharmacology', with dose-response, time-effect and side-effect profiles not unlike those of non-placebos and, indeed, often related to the comparison non-placebo.

A placebo response is, literally, a response to the administration of a known placebo. That known placebos can exert therapeutic effect is itself a remarkable phenomenon, balanced by the observation that in certain circumstances known non-placebo treatments may fail to exert their characteristic effect. The result of administration of a placebo may be detrimental or negative – termed a 'nocebo' response.

A placebo effect is a genuine psychological or physiological effect that is attributable to receiving a substance or undergoing a procedure, but which is not due to the inherent powers of the substance or procedure. Because such effects are attributable to the sociocultural context in which a treatment is delivered, to avoid confusion it may be preferable to use the term 'contextual effects' rather than placebo/nocebo effects. Such effects have been studied mainly with respect to pain but are involved in other clinical conditions.

Two important principles follow:

1. A placebo – now called contextual – effect does not require the administration of a placebo.
2. A non-placebo treatment will exert both a characteristic effect and a contextual effect.

Theories of placebo mechanism

Most experimental work deals with the placebo response, to allow inference of specific effect of an intervention. The greater is the difference between the verum (true) response and the placebo response, the more powerful is the intervention, so investigators seek to minimise the latter. This contrasts markedly to clinical practice, where an attempt is made to maximise the contextual (placebo) effect. Studies of placebo response in experimental situations have been used as models for understanding contextual effects in the clinical sphere.

The main current theories include classical conditioning, a predominantly non-cognitive process of learning through association; and expectancy, which allows access to conscious processes. The apparent tension between these two appears to have been resolved, in humans, by the learning-by-association proposed by the conditioned placebo model being mediated by expectancy.

> '...environmental settings (therapists, uniforms, syringes, pills, rituals) that have been associated with ameliorative effects may thereby become conditioned stimuli for the alleviation of symptoms.'

In brief, the conditioning model links an unconditioned stimulus (US), such as an effective drug that evokes an unconditioned response (UR), with features of the treatment setting, including persons, places or things, such that those neutral features themselves alone may then elicit a component of the UR. Thus those neutral stimuli become conditioning stimuli (CS) and elicit a conditioned response (CR). This reinforces the point made earlier that a non-placebo treatment will exert both a characteristic effect (UR) and a contextual effect (CR).

This model posits that environmental settings (therapists, uniforms, syringes, pills, rituals) that have been associated with ameliorative effects may thereby become conditioned stimuli for the alleviation of symptoms. Similarly, the association of neutral stimuli with aversive stimuli (such as a painful procedure or a tense interview) could condition negative or nocebo effects. This provides one basis for understanding variability in responses between and within subjects: individual learning differences arising out of having experienced particular forms of treatment in particular contexts. Through response generalisation, positive and negative CRs may potentiate or attenuate responses to subsequent treatments. It follows that to maintain a strong contextual effect (CR), the treatment environment must be associated regularly with effective treatment. The use of powerful non-placebos will enhance the contextual component of effect; the use of weak non-placebos

or of placebos will attenuate the non-placebo (UR) component of effect. This is particularly relevant in chronic conditions, where negative contextual effects from ineffective therapy may generalise, attenuating responses to a subsequent potent non-placebo, be that a treatment or a treatment provider.

Implications of placebo theory for the clinician

The model predicts that every interaction with health professionals plays a role in determining the contextual component of a person's current and future response to treatment. Expectations or faith or hope are largely learned through experience with the medical system: the challenge is how these effects can be harnessed.

Choice of size, colour, or route of administration of non-placebo treatments may manipulate response, as may pairing with specific suggestions. Expectancies related to the credibility of the therapist, of the therapeutic setting and of the specific treatment itself, including the credibility of the ritual of administration, may be enhancing factors. However, enhancing positive contextual effects does not extend to the use of known placebos.

The other side of this coin is to limit negative contextual (nocebo) effects. The theory predicts that the experience of unsuccessful treatments may contribute to extinction of the contextual component, which in turn may attenuate the effectiveness of even powerful non-placebos. This consideration implies that therapists should be aware of the effects of using treatments that have questionable efficacy. Furthermore, the failure of placebo treatments that are believed by the patient to be non-placebo treatments may lead to anxiety out of concern that the underlying condition is worse than appreciated. It follows that the use of known placebos for 'diagnostic' purposes is fundamentally flawed.

Expectancies related to the nature of the patient-therapist interaction may be the most important in this area. Factors include aspects of behaviour such as friendliness, consideration of patients' concerns, provision of time, clear explanations of diagnosis, prognosis and treatment, enthusiasm for treatment, and the choice of words, gestures, or other nonverbal forms of communication. It has been argued that interactional skills should be accorded as much priority in training as the attaining of medical knowledge (formalised as 'engage, empathise, educate, enlist and end').

Placebo theory informs the potential for manipulating both the contextual effect of non-placebo treatments and the response to known placebos. In pharmacotherapeutic studies, the comparison of parallel groups under double-blind conditions often fails to control for expectancy. To counter this, designs have been suggested to include expectancy controls. For example, half the subjects are told that they will receive the drug and the other half that they will not. Within each of these two groups, half actually receive the drug and the other half does not. The complicated interaction between expectancy and efficacy may also apply to within-subject designs. It has been shown that there is an order effect: placebos administered after effective non-placebos were rated as more effective than when administered before them. Modifications of design need to control for such order effects and for the expectancy of the administrators of the trial as well as those of the subjects. The extension of these principles to procedures, to invasive techniques including surgery and, indeed, to psychotherapy poses particular difficulty.

Further reading

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capital gains in women's health

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The RANZCOG GP Obstetric Advisory Committee is pleased to invite RANZCOG Diplomates to participate in the forthcoming Diplomates Days being held in association with the RANZCOG 2012 Annual Scientific Meeting in Canberra in September 2012.

Following a reflection of the need for ongoing educational sessions for both procedural and non procedural Diplomates, the RANZCOG has developed interactive sessions tailored specifically to meet the meet the needs of RANZCOG Diplomates.

The Diplomates Day programs will be held at Melbourne Convention Centre preceding the main scientific meeting on Saturday 8 and Sunday 9 September 2012.

The cost of attending Diplomates Day One and Diplomates Day Two is **A$440.00** per day. As participant numbers are limited, early registration is encouraged to avoid disappointment.

Diplomates are also welcome to attend the main scientific meeting, which will cover an array of topical and controversial subjects in contemporary obstetrics and gynaecology, including pelvic floor dysfunction, endometriosis, menopause, fibroids, preterm birth, intrauterine infection, the place of birth and early pregnancy complications.

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diplomates day one: obstetrics

Saturday 8 September 2012, 0900-1700

Preliminary Topics:

- Update on Labour Ward Management
- Update on Gestational Diabetes
- The Small Baby
- 1st Trimester Complications
- Maternal Collapse
- Update on Antenatal Care and Testing

diplomates day two: gynaecology

Sunday 9 September 2012, 0825-1630

Preliminary Topics:

- Polycystic Ovary Syndrome (PCOS)
- Medical and Surgical Options for Endometriosis
- Gynaecological Oncology
- Assessment and Management of the Patient with Vaginal Prolapse
- Adolescent Gynaecology
- Surgical Menopause

Painting the mice

Dr Gerald Lawson
FRANZCOG

A handful of scientists commit research fraud. Such cases, when exposed, generate widespread publicity, with career-ending consequences. Despite this, and the fact that many countries and institutions have introduced audit and disciplinary measures to prevent such fraud, further examples keep emerging.

In the 1970s, William Summerlin was a dermatologist at the Memorial Sloan-Kettering Cancer Center in New York, conducting research into transplantation immunology. He received much acclaim after announcing that he could transplant tissue from unrelated animals by keeping the tissue in culture for four to six weeks. He demonstrated this by breeding white mice with patches of fur from a black mouse. In 1974, Summerlin was exposed when lab assistants discovered that the patches on the mice could be removed with alcohol. The 'black patches' turned out to be the result of a black marker pen. Summerlin later attributed his deceptive behaviour to a combination of mental and physical exhaustion, and pressure to publicise positive results. As a result of the Summerlin incident, the term 'painting the mice' became a synonym for research fraud.

Prof Asim Kurjak was a highly regarded obstetrician in the former Yugoslavia. In 1974, he published a paper in a Yugoslav medical journal entitled: 'The effect of continuous lumbar epidural analgesia on the fetus, newborn child, and the acid-base status of maternal blood'. Fifteen years later, Dr Iain Chalmers became aware that it was a plagiarised article, with much of the text taken verbatim from a London study written in 1971. Chalmers' colleague, Dr Jim Neilson, discovered an additional layer of deception – Kurjak's paper was actually an amalgam of the 1971 article, combined with a similar 1973 article, both of which had been published in the *Journal of Obstetrics and Gynaecology of the British Commonwealth*.

Chalmers notified the University of Zagreb about this plagiarism. It responded by asking that 'as Professor Kurjak is a very distinguished expert, with significant contributions to ultrasound medicine, we would appreciate your tactful handling of the case.'

Chalmers went along with this request and did not publicise it. However, in 2002, over a quarter of a century after the original incident, he became aware that Kurjak had done it again, plagiarising a Norwegian student's PhD thesis for inclusion in a book he (Kurjak) had written. Chalmers regretted his earlier acquiescence in the request for 'tactful handling', and publicised the saga in the *British Medical Journal*.

Unfortunately, many of Kurjak's colleagues rose to his defence, saying that it all happened a long time ago, there are more important problems, no one ever died from plagiarism and so forth.

The 1980s

Stephen Breuning was a rising academic star at the University of Pittsburgh. By the age of 30, he had published widely on medications for hyperactivity and individuals with learning difficulties. He argued that certain tranquilizers did more harm than good. At one stage, he had published almost one-third of the material in this field. However, his supervisor, Dr Robert Sprague, became suspicious at the remarkable speed of his publishing output and asked for an investigation by the National Institute for Mental Health (NIMH).

The NIMH found that he had fabricated results and that 'none of the described studies of psycho-pharmacological treatment had been carried out'. Breuning blamed his behaviour on personal problems. He was convicted, in 1988, of scientific fraud and for making false statements on Federal grant applications, which is a criminal offence in the USA. Breuning was imprisoned for 60 days in a half-way house, and appears to have been the first person to serve time in prison for research fraud. This setback did not seem to derail his career. He resigned from the University of Pittsburgh and went on to establish a psychological practice in Rochester Hills, Michigan. His current website states that he is 'accepting new patients', but there is no mention of his misadventures in the 1980s.

Prof Michael Briggs was a graduate of Liverpool University, in the UK. He held a series of academic posts, as well as working for the pharmaceutical companies Wyeth and Schering. Briggs performed extensive research on the effects of oral contraceptives, especially the newly emerging triphasic contraceptives.

In 1973, he moved to Australia and, in 1976, was appointed professor of human biology at Deakin University, in Geelong. In the early 1980s, the chair of the Deakin University Ethics Committee, Dr Jim Rossiter, wrote to Briggs, querying his rapid recruitment of women on contraception. They were all perfect candidates: under 30 years old, within ten per cent of the ideal body weight, non-smokers, had never previously used the pill and were not on any medication. Not being satisfied with Briggs' reply, Rossiter made a formal complaint to the university. The case dragged on and Rossiter was subject to threatening phone calls in the middle of the night. In 1985, a new inquiry was begun. However, in September of that year, Briggs resigned from the university and the investigation was terminated. He moved to Spain and died 15 months later, at the relatively young age of 51, of liver failure. Three months before he died, perhaps realising he had not long to live, he gave an interview to journalist Brian Deer of the *Times*, in which he admitted to many of the charges laid against him.

John Darsee was a young researcher with a prolific output of publications. He worked at the lab of esteemed cardiologist Eugene Braunwald at Harvard University in the 1980s. In his first 15 months there, he produced five major papers. The discovery of his first fraud came to light when lab workers realised that he had changed laboratory data obtained over three hours to make it look as though the observations had been recorded over three weeks. Darsee said it was a single, isolated, foolish act and Dr Braunwild, after a preliminary investigation, unfortunately chose to believe him. That

he was guilty of long-standing fraud only came to light when it was realised there were significant differences between the results that Darsee had reported and those achieved by other laboratories that were working in the same field. This prompted an in-depth review by the National Institutes of Health, which discovered that Darsee had fabricated extensive amounts of data to create experiments that had never taken place. The review also discovered that he had been falsifying data since his medical student days. He subsequently worked at Ellis Hospital, New York, in critical care, on the condition that he did not carry out any research.

Dr William McBride, an Australian obstetrician, achieved fame when he wrote a letter to the *Lancet* in 1961, raising the alarm on thalidomide as a teratogen. This earned McBride nationwide praise and he was named 'Australian of the Year' in 1962. France's Institut de la Vie awarded him prize money for his discovery and, in 1972, he used the money to set up Foundation 41, a medical research organisation, investigating the causes of mental and physical handicap in babies.

In 1981, McBride published a paper suggesting that Debendox caused birth defects. Multiple lawsuits were launched by parents who felt their offspring had been handicapped by the mother taking Debendox during pregnancy. McBride was a willing expert witness in court for the claimants. However, two junior scientists working at Foundation 41, Dr Phil Vardy and Dr Jill French, discovered that they were the unwitting co-authors of the paper. They also noted discrepancies between the laboratory log data on Debendox and the data that McBride had published. A series of drafts of the paper revealed numerous changes in McBride's handwriting. They notified the Foundation's advisory committee of this finding. Nothing much happened until the ABC aired their complaints on the Science Show, broadcast by Norman Swan in 1987. This led to a formal investigation, which concluded that the scientific fraud charges were well-substantiated. He was de-registered from medical practice in 1993 on clinical and scientific misconduct grounds. In 1998, at the age of 71, he was reinstated.

Roger Poisson, was head of oncology, St Luc's Hospital, Montreal. In 1985, the *New England Journal of Medicine* published a five-year study on treatment of breast cancer: a randomised controlled trial on mastectomy versus lumpectomy, co-ordinated by the University of Pittsburgh, in which he was one of the authors.

Five years later, a project co-ordinator noted that, of the 89 hospitals involved in the trial, Dr Poisson's hospital had recruited a vastly disproportionate number of the patients: 354 out of 2163 (16.3 per cent); and that there were discrepancies in the patient data from this hospital. This was reported to the Office of Research Integrity (ORI), the US body that monitors and addresses research fraud. An audit subsequently revealed that patient records had been falsified.

In 1993, the ORI concluded that Dr Poisson was guilty of scientific misconduct. Poisson argued that what he had done was only 'white lies', that he had altered data because of his 'devotion to patients', so that they could be enrolled in the study; and that he was merely a scapegoat for the US medical establishment, which supported mastectomy, while he advocated lumpectomy. Poisson resigned from the hospital in April 1994.

Thinking of retiring from active practice?

If or when you do retire will you be:

- Completely and permanently retired from practice as a specialist obstetrician and/or gynaecologist?
- No longer acting as an expert witness in the field of obstetrics and gynaecology, except in:
  - cases for which you have already provided an opinion prior to the date of signing this Retirement Declaration; and
  - cases which deal with medical practices current during any time you were in active practice as a specialist obstetrician and/or gynaecologist and prior to signing the Retirement Declaration?

If you answered **YES** to all of the above then why not download the Retirement Declaration form: www.ranzcog.edu.au/fellows/cpdretirement.shtml .

What happens to my Fellowship if I sign the Declaration of Retirement form?
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- *Journal of Obstetrics and Gynaecology Research* (if you have elected to receive this)
- *RANZCOG Annual Report* (online)

What about my patient records?
See *College Statement No. WPI-8* on *Guidelines for Patient Record Management on the Discontinuation of Practice*: www.ranzcog.edu.au/womens-health/statements-a-guidelines/college-statements/508-guidelines-for-patient-record-management-on-the-discontinuation-of-practice-wpi-8-.html .

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If you are not in a situation where you can complete the Retirement Declaration form then you will continue as a Fellow of the College.

For further information or a copy of the Retirement Declaration form, please contact:

Val Spark
CPD Senior Coordinator
(t) +61 3 9412 2921
(e) vspark@ranzcog.edu.au

The 1990s

Malcolm Pearce was an assistant editor of the *British Journal of Obstetrics and Gynaecology* (*BJOG*), and a senior lecturer at St George's Hospital, London. Pearce had written a well-regarded textbook, Obstetric Ultrasound – How, Why and When. The professor at the hospital was Geoffrey Chamberlain, who was also the President of the Royal College of Obstetricians and Gynaecologists and editor of *BJOG*.

Pearce published a case report in 1994, claiming that he had removed a tubal ectopic pregnancy and then successfully re-implanted it within the uterus. The article reported how the pregnancy continued uneventfully to a normal delivery, the first recorded case of such a successful outcome. This was startling news to other members of the hospital staff. One of the anaesthetists reviewed the theatre records and could find no evidence that such a procedure had ever taken place. It transpired that Pearce had tampered with computer records to create a fictitious patient. The saga was complicated by the fact that Prof Chamberlain had agreed to attach his name to the article as co-author, even though he had nothing whatever to do with the case. He later said he did this out of 'politeness'.

Pearce was dismissed from the hospital and reported to the British General Medical Council (GMC), where he was found guilty of serious professional misconduct and struck off the medical register. Chamberlain was seriously discredited and felt compelled to resign from both the editorship and the presidency. These events led to a review of other papers by Pearce and four more were retracted.

Andrew Wakefield was the lead author in an article in the *Lancet* in 1998, stating that 12 children attending his clinic at the Royal Free Hospital in London had features of autism and colitis, which, in many cases, had followed earlier vaccination for measles, mumps and rubella (MMR). Wakefield held a television press conference to publicise his findings, an unusual action for a doctor. This generated widespread alarm in England and Wales and vaccination rates for MMR dropped from 92 per cent to 79 per cent over the next decade. However, epidemiological studies did not confirm any link between MMR vaccines and autism. Wakefield chose not to reveal to his co-workers or the editor of the *Lancet* a number of contentious issues. First, he had a lucrative financial arrangement with a law firm seeking to establish a link between MMR vaccine and autism. Second, many of the children studied were already on the books of the law firm and had been invited to come to his clinic, many from hundreds of miles away. One child came from California. Finally, Wakefield had previously lodged a commercial patent for a measles vaccine of his own, which would obviously have brighter commercial prospects if the MMR vaccine was discredited.

Nonetheless, in the *Lancet* and to the British Medical Research Council, Wakefield had declared that all the children in the study had been referred to his clinic through 'normal channels' by 'general practitioners, community paediatricians and child psychiatrists'; and that 'no conflict of interest exists'. In 2004, a journalist at the *Times*, Brian Deer, broke the story that, before publication, Wakefield had received £55 000 through the legal connection. Further payments to Wakefield eventually amounted

to £435 000. This revelation caused ten of the co-authors of the paper to dissociate themselves from its conclusion. Other charges against him were that he had ordered extensive invasive investigations on the children in the study, without any clinical reason or ethical approval. These investigations included lumbar punctures, MRIs, colonoscopes, colonic biopsies, EEGs and Schillings tests. In the face of mounting criticism, Wakefield remained defiant. However, in 2010, an enquiry set up by the GMC ruled decisively against him. Wakefield was de-registered as a doctor in the UK and the *Lancet* finally retracted his paper, 12 years after publication.

The 2000s

Dr Edward Erin, a consultant respiratory physician in his mid-forties, carried out research at the Imperial College Hospital in London. His 2006 paper 'The Effect of a Monoclonal Antibody Directed against Tumor Necrosis Factor A in Asthma' was cited by other writers in the field over 70 times. His downfall was not precipitated by any slip-up in his writings or by suspicious co-workers. Rather, it was his private life that was his undoing. A married man with two children, he had an affair with his medical secretary, which resulted in her becoming pregnant. She was keen to continue the pregnancy. In an attempt to cause her to abort, he spiked her tea and orange juice with methotrexate and misoprostol. She became aware that these drinks contained strange powder and took samples to the police. This led to criminal charges against Erin and, in October 2009, he was found guilty and sentenced to six years in prison.

Perhaps unsurprisingly, these events led Erin's peers to question the integrity of his research papers. In 2011, the *American Journal of Respiratory and Critical Care Medicine* retracted four of his papers owing to 'concern regarding the veracity of the data and the validity of his conclusions'.

Elizabeth Goodwin was a geneticist at the University of Wisconsin. In 2005, she asked her postgraduate student, Chantal Ly, to review some particulars in a grant application that Dr Goodwin was preparing. At this time Ly was seven years into her PhD program.

Ly realised that material in Goodwin's submission, which was described as 'unpublished data', had already been published in 2004. She showed this to a fellow PhD student, Garett Padilla. They noted other discrepancies, such as experiments that had not been performed. When approached about the errors, Goodwin dismissed them as a 'mix-up'.

The six postgraduate students in Goodwin's department were deeply troubled and discussed among themselves what they should do. It was decided that Ly and Padilla should meet with the head of the genetics department and show him the suspect data. This led to a formal enquiry that, in April 2006, reported 'evidence of deliberate falsification' in studies that had been funded by Federal grants, totalling US$1.8 million. Goodwin resigned shortly before the report was released.

The six postgraduate students suffered collateral damage. Their supervisors informed them that their years of thesis work would now be regarded as contaminated and advised that they should start from scratch on new theses. Of the six, three abandoned their PhDs altogether. Disillusioned, Ly took on a job as a lab technician, while Padilla abandoned science to enrol in law school.

Jon Sudbo, a Norwegian oncologist, published a study in the *Lancet* in October 2005 that claimed that the risk of oral cancer could be reduced with non-steroidal anti-inflammatory agents. The article was read by Dr Camilla Stoltenburg, the head of the Division of Epidemiology at the Norwegian Institute for Public Health, and also the sister of the Norwegian Prime Minister. She immediately realised that a statement in the article about utilising a particular Norwegian database could not be true, because the database had not been operational when the study was conducted. Stoltenburg passed this information on to the Radium Hospital in Oslo, where Sudbo worked. An inquiry was begun, which concluded that the 'bulk of Jon Sudbo's scientific publications are invalid due to the fabrication and manipulation of the underlying data material.' The article was retracted by the *Lancet* in February 2006. Dr Sudbo was stripped of his medical degree in November 2006, but this was re-instated in 2009, with the condition that he could not work in medical research.

It is hard to understand why intelligent people engage in such risky, fraudulent activity. The usual motivation appears to be a mixture of intense career and peer pressure to produce significant results and publications, financial incentives to obtain funding grants, and personality disorders or weaknesses, especially vanity and arrogance – the messiah complex.

There appear to be two main groups of fraudsters. The first group is the overly ambitious young researcher, determined to climb rapidly up the career ladder. The second group is more perplexing – senior doctors, often at the height of their careers, and often occupying prestigious positions. It is remarkable that they should jeopardise everything they have accomplished in their careers, for such little apparent gain. Perhaps they have been doing it for years, become addicted to it, and no longer know how to stop?

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Poidevin, Leslie (Leslie Oswyn), 1914-2006
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Barbour, AHF
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7. Operative gynecology. (2 vol work)
Peham, H & Amreich, J
Philadelphia: J B Lippincott Company, 1934
(English translation of Gynakologische Operationslehre)
Ex-library copy
$100.00

8. Uterotubal insufflation
Rubin, Isidor C. (Isidor Clinton)
London: Henry Kimpton, 1947
(1st edition, very good copy)
$50.00. Scarce

9. A textbook of obstetrics
Mayes, Bruce T
Sydney: Australiasian Publishing Company
1950. 1st ed.
(Slight rip in cover, rubbed edges)
$30.00
New and Revised edition 1965
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Springfield, ILL: Charles C Thomas, 1945
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Eden, Thomas Watts
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Speroff, Leon
Baltimore : William & Wilkins, 1973
(First ed of major gynaecological text which has since been republished many times)
$30.00

14. Colour atlas of gynaecology.
Beischer, Norman & Mackay, Eric
Sydney : WB Saunders Company, 1981
$25.00

15. A system of gynaecology: by man writers
Allbutt, Thoams Clifford (ed.)
London : Macmillan & Co Ltd, 1896
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Maguire, FA
Sydney : The Australasian Medical Publishing Company 1927
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18. British Obstetric and gynaecological practice
Holland, Eardley (Sir) editior
London : William Heinemann, 1955
Contributors include Peel; Mayes; MacLennan; Jeffcoate etc.)
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Saintly digressions

Prof Caroline de Costa
FRANZCOG

In the era before evidence-based medicine, the intercession of saints was regularly sought in times of sickness and suffering.

In the Middle Ages, the whole Christian population was interested in saints. Everyone prayed to them, visited their shrines, paid them honour and sang their praises. This was the era when most of the legends and beliefs concerning the saints were elaborated; many of these persist to this day.

All the Christian saints, major and minor, had some claim to miraculous powers or at least to good works. However, only some had particular medical prowess or interests; it was these who were invoked in the hope of a cure. The intercession of saints was regularly sought in times of sickness or suffering, and the more awful the torture undergone by the saint, the more efficacious the intervention was likely to be.

The story of St Agatha is a classical example of a saint with a reputation for expertise in matters affecting women's health. Born in the fourth century AD to a noble Sicilian family, Agatha abandoned her pagan upbringing, converted to Christianity and vowed her virginity to Christ. Following the edicts of Imperial Rome, the local Consul, a dastardly fellow called Quintian, tried to persuade her to renounce her faith, and attempted to seduce her by secretly administering an aphrodisiac, but she steadfastly rejected his advances. She was then imprisoned and tortured 'by rods, rack and fire'; however, she managed to preserve her chastity. As part of her torture her breasts were cut off; fortunately she was miraculously healed by a vision of St Peter, though she died in prison as the result of her suffering.

Very soon her cult became established: she appeared in all the reputable calendars of saints of the time, churches were established in her name in Rome and she was immortalised in mosaic in Ravenna. She became the patron saint of nursing mothers, who prayed for adequate supplies of milk, and of other women with breast diseases, who sought her intervention to affect a cure. In fact for more than a thousand years, women with breast problems turned to St Agatha for help.

What is said to be the veil of St Agatha is preserved in Florence Cathedral. She is still often represented in Italian churches, sometimes veiled, sometimes with her breasts uncovered or in a bowl. She is also beautifully portrayed in stained glass in the 13th-century cathedral of Clermont-Ferrand in France.

Agatha's effectiveness at curing breast disease would probably not long withstand the scrutiny of today's techniques of scientific medicine: all analyses would be retrospective only; no randomised controlled trial would be approved by an ethics committee; insufficient documentation exists for a meta-analysis; and histological proofs of diagnosis are non-existent. Yet hagiologists – those who study the lives of the saints – would affirm that over hundreds of years, many women did gain some relief, temporary or permanent, from prayers and visits to the shrines of St Agatha; certainly, there is a basis in our current knowledge of the physiology of lactation for believing that women might by prayer have increased their milk supply.

> '...the belief that saints could intercede with a higher god on mundane matters did provide, in an age when evidence-based medicine was unknown, hope and comfort; qualities still avidly sought by patients today.'

No doubt many of the 'cures' apparently obtained by pilgrimage or prayers to saints are easily explicable in terms of inaccurate diagnosis, placebo effect or of psychosomatic influences. However, the belief that saints could intercede with a higher god on mundane matters did provide, in an age when evidence-based medicine was unknown, hope and comfort; qualities still avidly sought by patients today.

In this way saints Leonard and Margaret might have assisted with difficult or prolonged labour, areas in which they were both believed to be effective. Leonard lived an ascetic existence in a forest in Noblac, France. One day King Clovis came to hunt in this forest, accompanied by his wife Clotilde, who was taken short in labour (perhaps she got her dates wrong). Fortunately, she was safely delivered by Leonard; so grateful was her husband the king that he granted Leonard as much land as he could ride around in one night on a donkey, on which the budding saint built an abbey. Leonard thus became the saint to be addressed by pregnant and birthing women generally, whereas St Margaret is the particular saint of childbirth.

Not much is known about the origins of Margaret, although she is supposed, like Leonard, to have lived in the fifth century. She is reputed to have been the daughter of a pagan priest from Antioch, who turned her out of home when she converted to Christianity, whereupon she became a shepherdess. Several dramatic stories were told about her, including one of her having been swallowed by a dragon, which later split asunder, freeing her. She is often depicted in churches and cathedrals in the company of the dragon.

Reading stories of the life of St Margaret aloud to labouring women was said to reduce the pain of contractions, and frequently candles were lit for the saint during difficult labours. When it

Typical depictions of Saints Margaret (left) and Agatha (right): St Margaret, the patron saint of childbirth, was prayed to during difficult labours, while St Agatha was the patron saint of nursing mothers.

seemed that prayers to her had been answered it was usual to give thanks to St Margaret by placing the dried umbilical cord on her shrine postpartum.

Another saint of interest to obstetricians is St Anthony. Ergot, the product of a fungus that grows on grain, especially rye, has been known for hundreds of years to be useful at bringing about uterine contractions and, therefore, effective at preventing and treating postpartum haemorrhage. However, bread made from affected rye can also be the cause of acute ergot poisoning and there were extensive epidemics of 'ergotism' in Europe in the Middle Ages, the origins of which were not recognised at the time. The strongly vasoconstrictive properties of ergot caused intense burning pain in sufferers of ergotism, as well as gangrene of the hands and feet, which in severe cases became black and mummified and dropped off. Spontaneous abortion also frequently occurred.

St Anthony himself was a third-century Egyptian hermit who lived a simple life in the desert by the Red Sea. In his own lifetime he had no connection with ergotism, but his name was taken by an order of monks, the Antonite Hospitallers, which was founded in the 12th century. These monks travelled widely across medieval Europe, collecting alms and establishing hospitals that, among other things, treated sufferers from ergotism, which became known as St Anthony's fire. What were said to be the saint's bones were sprinkled with water or wine that was then drunk by those afflicted, with apparently good results. It seems, however, more probable that they were cured by the Hospitallers providing a diet free of contaminated rye. Whatever the cause of such cures, spontaneously amputated limbs were often left at St Anthony's shrines as offerings of thanks and evidence of the saint's powers.

Readers of *O&G Magazine* may also like to know of St Stephen – who is the saint to pray to for relief of a hangover. Stephen is something of a generalist – he is good for all kinds of headaches and, having been stoned to death, he has skills in the area of renal and ureteric colic and other symptoms of urinary stones. Other saints of interest include Catherine, the patron saint of nurses. She is renowned for her torture on the wheel (although how many Australian children now would know what a Catherine wheel is?) In fact Catherine's wheel of torture broke down, injuring spectators, and she was subsequently beheaded. Milk not blood flowed from her severed head, hence the nursing association. St Vitus is the patron saint of those who suffer epilepsy and fits, though whether his powers extend to eclampsia is not recorded. St Barbara protects against sudden death. Her father, vehemently opposed to his daughter's conversion to Christianity, was struck dead by lightning; his daughter therefore became protectress against such calamities.

> 'Reading stories of the life of St Margaret aloud to labouring women was said to reduce the pain of contractions, and frequently candles were lit for the saint during difficult labours.'

If all else fails, there is always St Jude, patron saint of hopeless cases, who restored speech to the mute and cured leprosy. Even today, praying to St Jude may be as effective as some complementary medical therapies. And, like all his saintly colleagues, Jude offers comfort and consolation, qualities that should not be overlooked by practitioners of evidence-based medicine today.

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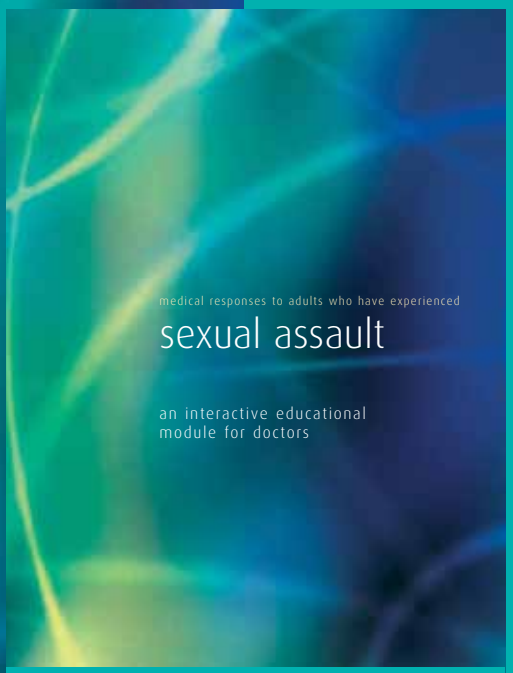
medical responses to adults who have experienced

sexual assault

an interactive educational module for doctors

Medical professionals who have good quality training are well-placed to respond appropriately to adults who disclose sexual assault, thus providing the opportunity to mitigate longer term health impacts for these people.



Women who experience sexual assault look to their doctors to recognise the effects of sexual assault, raise the issue with them and respond in a supportive way by addressing the health effects—just as doctors would respond supportively and professionally to any other health issue.

'Medical Responses to Adults Who Have Experienced Sexual Assault: an Interactive Educational Module for Doctors' is an educational tool designed to prepare doctors to respond to patients who have been sexually assaulted.

Collaboratively produced by a working party of experts in the field and representatives from eight medical colleges, as well as the contributions of numerous specialist advisors, this module is a high quality educational tool incorporating assessment tasks, activities and readings.

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- a section on self-care for doctors and contacts for referrals to sexual assault services, plus a list of further resouces and additional reading in specialist areas

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The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

RANZCOG
Honours and Awards

Call for Nominations: Closing Date 30 June 2012

College Fellows are invited to submit nominations for the awards of Honorary Fellowship, Distinguished Service Medal and Certificate of Meritorious Service for consideration of the RANZCOG Honours Committee and Council in July 2012. Information on the categories of College awards is as follows.

1. Honorary Fellowship

1.1 Medical practitioners, not already FRANZCOG, who have made an outstanding contribution to the study or practice of medicine in the field of women's health. In general this honour should be reserved for those who have not had their contribution otherwise recognised.

1.2 Persons who are not medical practitioners who have made an outstanding contribution to the study or practice of medicine in the field of women's health. In general this honour should be reserved for those who have not had their contribution otherwise recognised.

1.3 Fellows of renown of other Medical Colleges.

1.4 Persons who are not medical practitioners who have made an outstanding contribution to the work of the College.

Honorary Fellowship is to be bestowed by Council on recommendation by the Honours Committee. Honorary Fellows are not required to pay a registration fee or annual subscription and are not required to undertake continuing professional development. They are entitled to receive College publications. Members or Associate Members of the College may be awarded Honorary Fellowship.

2. President's Medal

This should generally be awarded once per Council term toward the end of that term, but there may be more than one recipient under exceptional circumstances. It is awarded to Fellows of the College who have made an outstanding contribution to the work of the College. Nominations for this medal are made by the President. It is awarded by Council on recommendation by the President and Honours Committee.

3. Distinguished Service Medal

This is awarded to Fellows of the College who have made a significant contribution to College work. This may be a more frequent award than the President's medal. It is awarded by Council on recommendation by the President and Honours Committee. Awarding of a Distinguished Service Medal does not preclude awarding of a President's medal at a later date.

4. Certificate of Meritorious Service

This is awarded to persons other than Fellows of the College who have made a significant contribution to College work. It is awarded by Council on recommendation by the Honours Committee.

Process for Nomination

- Nominations for Honorary Fellowship, RANZCOG Distinguished Service Medal or RANZCOG Certificate of Meritorious Service must be made by a Fellow of the College, and submitted in writing to the President by **30 June 2012**.
- Nominations must include full details of the reason for the nomination and a curriculum vitae.
- Nominations must be seconded by a detailed letter of support from another Fellow of the College.
- Either the nominator or the seconder must be a Councillor or a Regional Committee Chair.

For further information on the nomination and evaluation process, please contact:
Penelope Griffiths, Director, Corporate Services, ph: +61 3 9251 9030 or 9417 1699;
fax: +61 3 9419 0672; email: pgriffiths@ranzcog.edu.au .

What's new in contraception?

An overview of current and future contraception options.

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Medical Director
Family Planning NSW

The range of contraceptive methods has expanded in the last few decades so that women, and their partners, are increasingly likely to find a method that is a 'good fit'. However, the concept of what makes an 'ideal contraceptive' is by no means universal. While it may seem obvious that a contraceptive method should be effective, affordable and with minimal risks and side effects, other attributes such as reversibility, the possibility of detection by others and additional 'non-contraceptive' benefits may be desirable for some, but not for others. This article provides an overview of recent developments in contraception as well as a glimpse of what to expect in the future.

Australian women have been taking the combined oral contraceptive pill (COCP) since 1961, although somewhat astoundingly it was then only available to women who could prove that they were married! Early COCPs contained much higher hormone doses and had higher risks and more side effects. The quest has, therefore, been to reduce the hormonal dose while maintaining efficacy. While early pills had the equivalent of 150mcg of ethinyl estradiol (EE), today's low-dose pills contain between 35 and 20mcg EE.

The most serious COCP-related risk is venous thromboembolism (VTE), a 'hot topic' in recent years. Estimates of the background rate of VTE in women of reproductive age who are neither pregnant nor postpartum vary from 0.7 to 13.5 per 10 000 women years[1] and use of the COCP appears to increase the risk approximately two- to three-fold over baseline.[2] When discussing VTE risk it is crucial to set the risk in context and explain that the absolute risk is extremely low, far lower for example than the VTE risk in the postpartum period.

While lowering the EE dose from 100 to 35mcg was definitively associated with a reduction in VTE risk, the effect of reducing EE yet further to 20mcg is less clear. Any potential safety benefits in relation to a reduction in EE dose also need to be weighed against the loss of cycle control that occurs as the oestrogen dose drops. Unpredictable bleeding is certainly a side effect that most women would rather avoid.

The effect of different progestogens on VTE risk is also unclear. COCPs containing the earliest progestogen, levonorgestrel (LNG), remain the 'gold standard' in relation to risk. Newer pills containing drospirenone have been under scrutiny recently. While studies are conflicting, on balance there appears to be an increased VTE risk with dropsirenone COCPs.[3] However, the fact remains that the absolute risk for all the COCPs on the market is extremely low for women who are not contraindicated for the use of oestrogen. Until 2010 all COCPs contained EE, but this has now changed with the introduction of pills with oestradiol or its pro-drug, oestradiol valerate (marketed as Qlaira® and Zoely®, respectively). So what, if any, are the potential advantages of these newer pills? In the research setting, oestradiol-containing COCPs have a reduced impact on liver metabolism, including clotting factors.[4,5] However, it is important to be aware that 'real life' evidence for any safety benefit over EE-containing pills is pending. Large post-marketing surveillance studies will provide observational data in a few years.

Some women may choose a particular COCP for its additional non-contraceptive benefits, for example, for acne control or reduction in heavy menstrual bleeding (HMB). However, evidence for the benefits of one pill type over another is generally lacking and finding the most appropriate COCP to suit an individual woman's circumstances is often a matter of 'trial and error'.

While all COCPs will potentially reduce blood loss, as a result of a placebo-controlled trial showing a significant reduction in the

A selection of contraceptives – there is no one method that is suitable for all.

DMPA is given every three months, but can affect bone density.

duration and quantity of bleeding over 13 cycles, the oestradiol valerate/dienogest pill has gained an indication for the management of idiopathic HMB in women requiring contraception.[6] This results from the potent endometrial effect of dienogest in combination with oestradiol valerate in a quadriphasic regimen with a shortened placebo break. This COCP may, therefore, be a suitable choice for appropriately investigated perimenopausal women (at least those who can afford its non-PBS listed cost). The dosing regimen also results in more complex 'missed pill rules' so it would not be an ideal choice for young women starting the pill for the first time.

Extended COCP regimens

When the COCP was first developed, the social context of the day demanded that it should 'mimic the natural cycle' with a guaranteed monthly withdrawal bleed. Women have been pretty much stuck with this outdated concept ever since, with most pill packs providing 21 hormonal and seven placebo pills. This is now changing with the advent of COCPs with either four placebos (Yaz® and Zoely) or two placebos (Qlaira). Why is reducing the placebo break useful? Apart from potentially reducing the duration and quantity of withdrawal bleeding, it can also reduce hormonal withdrawal symptoms such as pelvic pain and headache and provide a greater 'margin for error' if pills are forgotten at the beginning of the next pack.

Many women have been skipping their placebo pills for years in order to avoid withdrawal bleeds and the practice of running three pill packs together without placebos is well documented. Extended cycle packs with either 84 hormone and seven placebo pills or 365 hormone and no placebo pills are available in other countries and prolonged use of the pill for up to 12 months has been shown to be both safe and acceptable.[7] Family Planning NSW is also comparing continuous use of low-dose pills or vaginal rings (replaced every four weeks) in a 'bleeding-signalled regimen' until four days of continuous spotting and/or bleeding occurs at which time the pill is stopped or ring removed on the fifth day and restarted five days later. Trial results, including bleeding patterns and acceptability, will be available in 2013.

> 'Since women may use contraception for approximately half of their lifetime, it is essential that we provide careful evidence-based advice...'

Vaginal rings and patches

The vaginal ring offers an alternative contraceptive delivery system that is acceptable to women, although use may be limited by cost as it is not available on the PBS. The vaginal ring (available as NuvaRing®) allows for a reduction in EE dose to the equivalent of 15mcg per day, although this does not translate into a reduced VTE risk. Women can hook up to an SMS reminder system for removal and reinsertion timing – contraceptive apps are definitely the way of the future!

'Back to back' removal and immediate reinsertion of the ring every three to four weeks is useful for women choosing to avoid withdrawal bleeding. A Population Council multinational trial of a vaginal ring containing sufficient hormones for 12 months of use will hopefully result in the availability of this useful product in the not-too-distant future.

Contraceptive patches are unavailable in Australia, except in our research setting. Again, despite their low-dose of hormones, they are not associated with a reduced risk of VTE.

The era of LARCs

Long-acting reversible contraceptives (LARCs) are methods administered less frequently than once a month. Since they are independent of the need to remember to 'do something' at the time of intercourse or on a daily basis, their 'typical use' effectiveness is close or identical to their effectiveness under research conditions.

The earliest LARCs are the injectables, principally depot medroxyprogesterone acetate (DMPA) given every three months. DMPA remains a useful method of contraception as it is effective, cheap and undetectable by others. That said, DMPA has had its detractors over the years in relation to its bone density effects (reversible in women of mid-reproductive age and not related to an increase in fracture risk) and the fact it is not immediately reversible. New approaches including reduced hormonal doses as well as subcutaneous delivery methods may be the way of the future.

Contraceptive implants

Contraceptive implants provide highly effective, cost-effective and immediately reversible contraception for up to three years (with no significant impact on bone density). While implants have been available in Australia since 2001, 2011 saw the change from Implanon® to Implanon NXT®. The difference lies in the applicator, designed to minimise deep insertions leading to difficult and potentially risky removals. Implanon NXT also contains barium sulphate to allow for visualisation in the case of deep insertion (somewhat counterintuitive if the new applicator really does minimise deep insertions, but the intention is good).

Unacceptable vaginal bleeding is the most significant side effect and can lead to early removal. Frequent and/or prolonged heavy bleeding affects approximately one in five women.[8] Women can be informed that the bleeding pattern in the first three months of use is broadly predictive for future bleeding patterns and that those with an unfavourable initial pattern have a 50 per cent chance of improvement.[8] The evidence-base for the management of unacceptable bleeding patterns is limited and recommendations also follow a pragmatic approach.[9,10] If not contraindicated, use of a COCP for up to six months (or longer if required) can provide a 'band-aid' solution for current bleeding, but will not have any long-term effect when stopped. Similarly, a five-day course of mefenamic acid or tranexamic acid may shorten the duration of a current bleeding episode, but will not affect the subsequent bleeding pattern.

Intrauterine devices

Intrauterine contraception has been available for decades, although the latest devices are a far cry from earlier prototypes such as the Dalkon Shield. It is certainly time to lay some of the misconceptions about intrauterine devices (IUDs) to rest. For example, the increased risk of pelvic infection is low and appears to be mainly confined to the first 20 days after insertion[11,12] after which the risk reverts to the woman's background risk for infection. There is no evidence of an increased risk of subsequent infertility for women using an IUD.[13]

Medicare data show that use of the LNG-releasing IUD (Mirena®) is increasing, presumably due to its delivery of highly effective, cost-effective contraception as well as its menstrual blood loss benefits.

A smaller device that releases the equivalent of 12mcg rather than 20mcg of LNG per day is currently under trial. This new device, hopefully available in 2014, may prove especially suitable for young nulliparous women for whom the IUD is an acceptable and appropriate method of contraception.

Copper-IUDs, while less prevalent than the LNG-IUD, have a valuable place in the contraceptive arsenal for women requiring a highly effective long-acting hormone-free method. Copper-IUDs can also be used to provide postcoital emergency contraception for up to five days after unprotected intercourse. The practicalities of timely access in the primary care setting need to be addressed before their use in this context becomes a realistic proposition. However, family planning organisations are currently expanding their delivery of IUD-insertion training for GPs so hopefully these barriers will be reduced in the future.

Condoms and the importance of dual protection

Condoms, both male and female, are the only contraceptives that simultaneously protect against sexually transmissible infections (STIs). As a contraceptive method they have a failure rate of up to 18 per cent, mainly because of incorrect or non-use. For women at risk of STIs they can be 'doubled up' with another effective contraceptive method such as an IUD or implant. The only female condom available in Australia is made of polyurethane, but its use is limited by lack of availability and cost (approximately $3 each). Newer prototypes include a condom made of a nitrile polymer that optimistically promises 'quieter use'.

Emergency contraception – new horizons

The most commonly used emergency contraceptive method is a single 1.5mg dose of LNG taken as soon as possible after unprotected intercourse. While almost all Australian women in a recent survey had heard of the emergency contraceptive pill (LNG-ECP), unfortunately fewer than half were aware that it was available without a prescription at the pharmacy.[14]

The LNG-ECP primarily acts to prevent or delay ovulation by interfering with follicular development and preventing the LH surge.[15] It appears to have no effect once the LH surge has commenced. It is licensed for use up to 72 hours after unprotected intercourse, but WHO recommends it can be used up to five days after intercourse.[16] While recent data suggest delaying administration until the fifth day increases the risk of pregnancy more than fivefold compared with administration within 24 hours[17], the threshold for use should be low.

An alternative oral emergency contraceptive has been available in Europe since 2009, in the form of the selective progesterone receptor modulator, ulipristal acetate (UPA). UPA is marketed as ellaOne® and is licensed for use up to 120 hours after unprotected intercourse or contraceptive failure. It works primarily in the same way as the LNG-ECP by inhibiting or delaying ovulation, but also may cause alteration to the endometrium. Research suggests it has superior efficacy to the LNG-ECP at 24, 72 and 120 hours.[18] Hopefully Australian women will be able to access UPA soon.

In conclusion

Since women may use contraception for approximately half of their lifetime, it is essential that we provide careful evidence-based advice about the variety of available options. The 'best fit' for an adolescent is likely to differ from the method chosen as a postnatal 32 year old and then, later, as a perimenopausal 49 year old.

New developments in technology coupled with well-designed research trials will help ensure that Australian women and their partners are able to find a contraceptive method that best suits their stage and situation in life.

Declaration of interest

Deborah Bateson has provided expert opinion for MSD and Bayer Healthcare as part of her role as medical director of Family Planning NSW. She has been supported to attend conferences by BayerHealthcare.

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Uterine fibroids

Dr Brett Daniels
FRANZCOG

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Few gynaecological conditions cause as much unnecessary fear and confusion for patients as fibroids. We examine the latest thinking on the management of this common pathology.

Leiomyomata (fibroids) of the uterus were among the first specific gynaecological pathologies ever described. Surgical removal of fibroids (myomectomy) was first described at the end of the 19th century, although at that time the mortality from the procedure approached 15 per cent.[1] We now recognise that fibroids are extremely common, although an exact prevalence is difficult to provide. Ultrasound studies have described an increasing prevalence as the age of women examined increases, with an overall lifetime incidence of about 50 per cent. However, if histological criteria are used, as many as three quarters of women will have fibroids.[2]

The aetiology of fibroids is only partially understood. They are clonal, meaning that each individual fibroid has arisen from a single myometrial cell.[2] Fibroids are common in women of Afro-Caribbean descent, although the reasons for a racial difference are not clear. It seems likely that multiple factors are involved in regulating the growth of fibroids, in particular the sex steroids progesterone and oestradiol. It may be that the muscle cells that compose fibroids have increased expression of oestrogen receptors.[3] Multiparous women are more likely to have fibroids, as are those with a longer menarche-menopause interval. Other conditions associated with an increased risk of fibroids include obesity, polycystic ovary syndrome, diabetes and hypertension.[1]

Diagnosis of fibroids

Many women will undergo examination and investigation after reporting such symptoms as heavy menstrual bleeding, pelvic 'pressure' and, sometimes, an incidental finding of a pelvic mass. In some cases, fibroids are not suspected and are incidentally discovered during investigation of unrelated problems. Ultrasound is the most commonly used diagnostic modality and has both high positive predictive and negative predictive values.[4] Ultrasound is very useful in the triage of pelvic tumours, allowing sensitive and specific differentiation from uterine malignancy and ovarian masses. Other modalities, such as magnetic resonance imaging (MRI) and computed tomography imaging, sometimes provide additional information that can assist in planning treatment, such as evidence of effect on the ureters.

There are differing classifications of fibroids, depending on their size and location in the uterus. However, the most clinically useful classification is: submucous (fibroids that distort the uterine cavity); intramural (where there is no component in the uterine cavity and the majority of the fibroid is contained within the uterine wall); and subserous (where the majority of the fibroid is without the uterus, commonly on a pedicle).

> 'Since fibroids are manifestly common and most women are completely asymptomatic, the majority of women do not need any form of treatment apart from reassurance.'

Management of fibroids

Since fibroids are manifestly common and most women are completely asymptomatic, the majority of women do not need any form of treatment apart from reassurance. However, when there is a clinical symptom complex associated with the fibroids, it may be necessary to offer treatment. Such clear-cut symptoms include heavy menstrual bleeding or sometimes a sensation of 'pressure' within the pelvis. However, there are also associations between the presence of fibroids and either infertility, early pregnancy loss or late pregnancy complications, and sometimes all of these.

Let's begin with the simpler situation of submucous fibroids. These are unequivocally associated with heavy menstrual bleeding owing

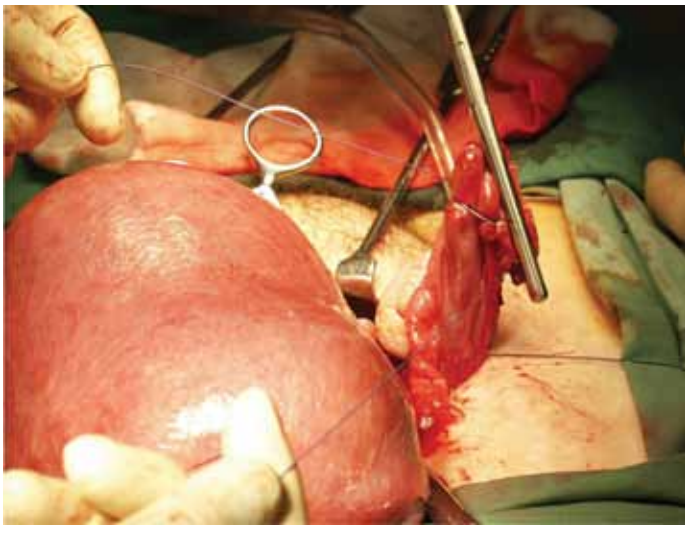

Figure 1. Abdominal hysterectomy for a large, fibroid uterus. Massive uterine enlargement from uterine fibroids is one of the commoner indications for abdominal hysterectomy in the era of minimally invasive surgery.

to the increase in endometrial surface area and the common presence of vessels coursing over the surface of the fibroid. It is also likely that the normal mechanisms that limit the duration of menstrual periods – coordinated occlusion of the spiral arterioles supplying the endometrium by myometrial contractions – is disrupted. Submucous fibroids are also associated with fertility delays, implantation failure and early pregnancy loss.[5] Medical therapy where fertility is a consideration is usually contraindicated, except in acute situations, since treatment with progestins or GnRH analogues is incompatible with pregnancy. The most useful therapy is hysteroscopic resection. Larger fibroids may be managed with pre-operative GnRH analogues to help reduce the size and vascularity of the fibroid.[1] Hysteroscopic surgery has been complicated by intrauterine adhesions and perforation, so careful counselling and consideration is required.

Decision-making with intramural and subserous fibroids can be more difficult. Therapies can be divided into medical, interventional imaging and surgical. Medical therapies include GnRH agonists and antagonists, selective oestrogen receptor modulators (SERMS), the levonorgestrel-releasing intrauterine system (Mirena®) and more experimental therapies, including mifepristone and cabergoline.

Medical therapy of fibroids

Prolonged use of GnRH agonists such as goserelin (Zoladex™), leuproline (Lucrin™), and naferelin (Synarel™) has been reported to reduce the volume of fibroids. However, the side effects of prolonged GnRH agonist therapy severely limit their use. More prolonged therapy can be maintained with 'add back' of the oestrogen β-receptor (ERβ) agonist tibolone.[6] Mirena is commonly successful in reducing menstrual flow, but the effect on the volume of fibroids is minimal.[1]

Interventional imaging

Two interventional techniques have entered common use in the management of fibroids – uterine artery embolisation (UAE) and high-intensity focused ultrasound (HIFU). Embolisation of the uterine arteries aims to reduce the volume and clinical effects of fibroids while preserving the uterus. There are various techniques for the procedure, but in all cases a unilateral femoral artery catheter is passed by an interventional radiologist and selective catheterisation of the uterine arteries or branches identified as supplying fibroids is then undertaken. The vessels are then embolised with (usually) non-absorbable materials such as polyvinyl alcohol (PVA) particles. When used to treat fibroids associated with heavy menstrual bleeding, the results are good in the short term.[7]

There have been a number of concerns raised about the effect of UAE on subsequent pregnancy, however. Although studies are limited, a number of pregnancies have been reported in women who have undergone UAE and these are characterised by higher rates of preterm birth, malpresentation and caesarean delivery.[7] However, it is difficult to know whether these women would have been able to become pregnant without the procedure and, if they had, how these pregnancies would have progressed.

HIFU, where high-intensity ultrasound has been used to treat fibroids, can usually only target one fibroid at a time and has been

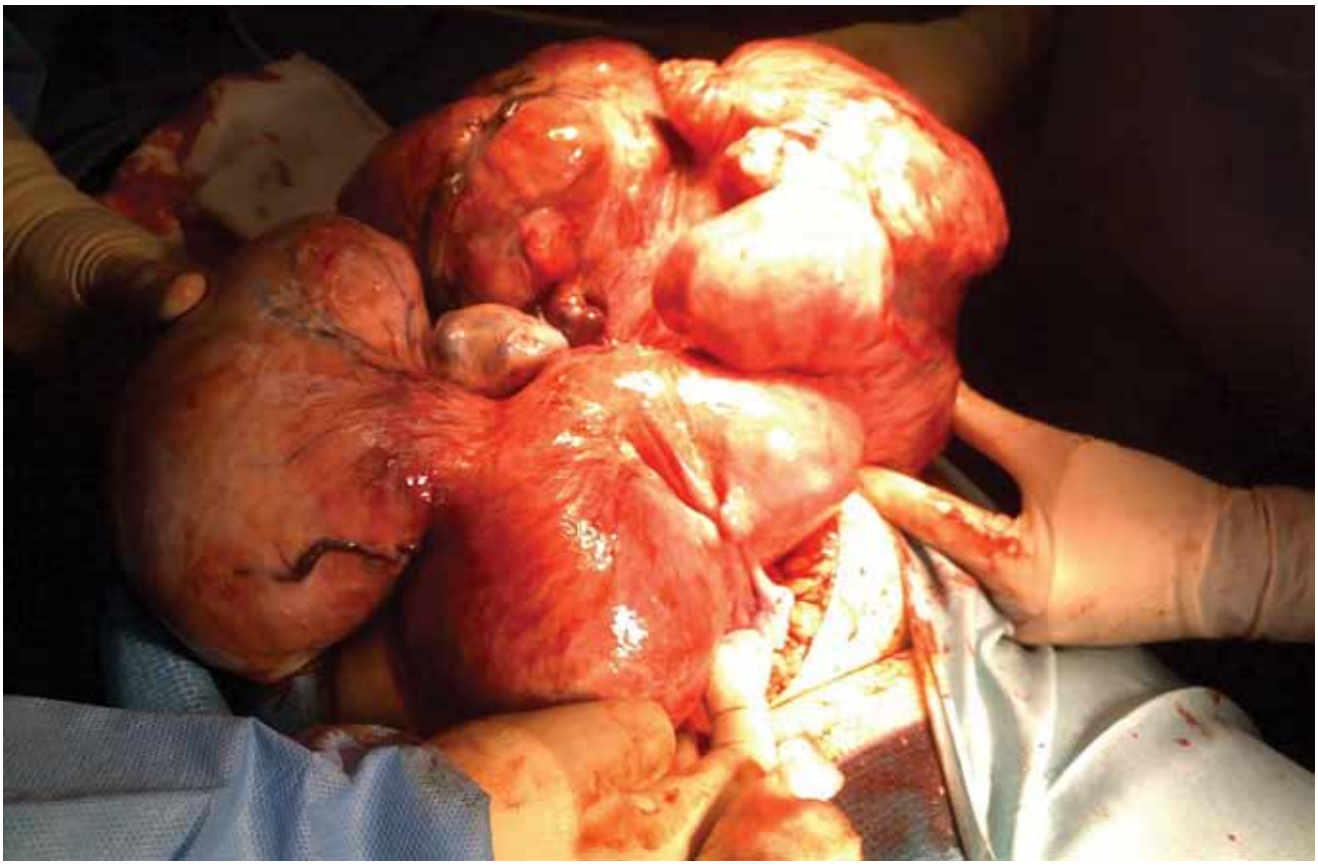

Figure 2. A massive fibroid uterus at hysterectomy. Preservation of the ovaries in this situation can be difficult for even the most experienced surgeon.

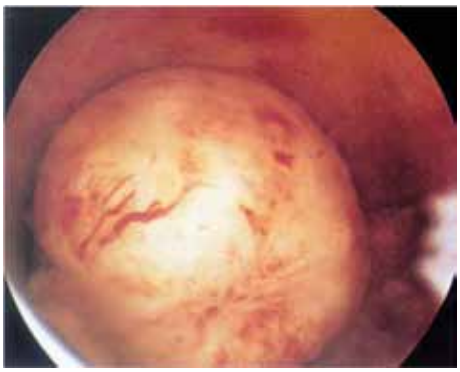

Figure 3. A submucous fibroid. Note the large vessels coursing across the surface. Hysteroscopy surgery is the only effective method of dealing with this type of fibroid while still preserving fertility.

associated with burns to the skin. More data are required before the value of HIFU can be fully assessed.

Surgical treatment of fibroids

Two surgical therapies are available – hysterectomy and myomectomy. Hysterectomy is obviously a definitive treatment, but non-surrogate pregnancy afterwards is not possible. It is certainly not an option for younger women desiring preservation of fertility. In general, vaginal hysterectomy is the preferred route and large uterine volume is not a contraindication.[8] However, laparoscopic hysterectomy (of whatever level) may be associated with reduced blood loss,and is certainly superior if removal of the adnexal structures is required at the same time.

Myomectomy aims to preserve the uterus and, with it, fertility in general terms. It can be performed by the abdominal or laparoscopic route. Laparoscopic myomectomy is associated with shorter inpatient course, more rapid recovery and return to normal function and reduced need for transfusion.[8] However, there appear to be no benefits with respect to subsequent chance of pregnancy and complications thereof.

Fibroids and infertility

The Australasian CREI Consensus Expert Panel on Trial evidence (ACCEPT) in 2011 published a consensus statement on fibroids in fertility, which now forms a College statement.[9,10] When infertility is an issue the group recommend using MRI, sonohysterography or hysteroscopy for determining whether there is uterine cavity involvement by the fibroid. The group reported that subserosal fibroids did not affect fertility outcomes, while intramural fibroids may be associated with reduced fertility and an increased miscarriage rate. There was however insufficient evidence to show that myomectomy for intramural fibroids improved fertility outcomes. Submucosal fibroids are associated with reduced fertility and increased miscarriage and hysteroscopic myomectomy is likely to improve outcomes.

The group recommended myomectomy for infertile women if: a woman is infertile and has submucosal fibroids, or a woman has symptomatic fibroids, or a couple has multiple failed cycles of assisted reproductive technology and the female partner has intramural fibroids. The group also concluded that medical treatment delayed efforts to conceive and was not recommended, other than using GnRH analogues in the short term to correct preoperative anaemia or reduce fibroid volume and that treatments such as uterine artery embolisation, MRI-guided focused ultrasound surgery and radiofrequency ablation should only be used in the setting of approved clinical trials.

Fibroids and cancer

Patients often ask if fibroids should be removed because of the risk of cancer. Leiomyosarcoma is rare, particularly in premenopausal women, with only 0.1 per cent of uterine smooth muscle tumours being malignant leiomyosarcomas.[11]

A rapidly enlarging myoma in a postmenopausal woman has a higher likelihood of malignancy, with leiomyosarcoma being reported in 1.4 per cent to 1.7 per cent of women undergoing hysterectomy in the sixth or seventh decade of life.[12] In the vast majority of cases leiomyosarcoma arises *de novo*, not from pre-existing fibroids, although rare case reports do exist of leiomyosarcoma arising within fibroids.[11,12]

Summary

Uterine fibroids are incredibly common and should almost be considered a normal part of the anatomy for women aged over 40 years. In the majority of cases, fibroids are completely incidental findings and women are asymptomatic. When symptoms are present, a decision needs to be made about whether fertility preservation, either in the short or long term, is required as this is a major driver of decision-making. Conservative medical therapies are usually incompatible with pregnancy. If the symptoms are related to recurrent pregnancy loss or fertility delays, surgical treatment is usually indicated. Other treatments, such as UAE, may have a role, but data are limited when compared to myomectomy in these circumstances. Definitive treatment is by hysterectomy, with its obvious potential disadvantages. As always, the treatment has to be individualised to the patient.

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Journal Club

Had time to read the latest journals? Catch up on some recent O and G research by reading these mini-reviews by Dr Brett Daniels.

Postmenopausal bleeding investigation

Postmenopausal bleeding is a common clinical problem, with the exclusion of endometrial cancer being the primary aim of investigation. Current investigation commonly involves transvaginal ultrasound determination of endometrial thickness, with a thickness of less than 4–5mm being unlikely to be malignant. The authors of this study report that 3–10 per cent of postmenopausal women have an endometrium that cannot be adequately visualised on transvaginal ultrasound. This study followed nearly 4500 women referred with postmenopausal bleeding to a UK gynaecological oncology unit. In 174 women (four per cent) the endometrial thickness was unable to be clearly visualised with transvaginal ultrasound, most often due to fibroids obscuring the view. All of these women received endometrial sampling either with Pipelle® or at hysteroscopy. While the majority (71 per cent) of women in this group had benign pathology, 15 per cent had malignancy detected at endometrial biopsy. These results confirm the standard approach that endometrial sampling should be performed if the endometrial thickness cannot be determined by ultrasound.

Burbos N, Musonda P, Crocker, SG, et al. Management of postmenopausal women with vaginal bleeding when the endometrium cannot be visualized. *Acta Obstet Gynecol Scand* 2012: March 24.

Silicon pessary to prevent preterm labour

Spontaneous preterm labour remains a major cause of perinatal mortality and morbidity and the prevention of preterm labour is the focus of researchers worldwide. This study is a randomised open label controlled trial of a cervical pessary as a means to reduce preterm labour. The pessary in question is a silicone ring with an external diameter of 70mm and an internal diameter of 32mm that is designed to fit around the cervix. Women with a singleton pregnancy were offered cervical length measurement during a routine second trimester ultrasound and those with a cervical length of <25mm were offered enrolment in the trial. Outcome data were available for a total of 380 women randomised to either the pessary or expectant management group. The pessary was removed during the 37th week of gestation. There was a significant difference in delivery before 34 weeks gestation with 12 women in the pessary group delivering, compared with 51 in the expectant management group (OR=0.18, CI 0.08–0.37; p<0.0001). There was not a significant effect for obstetrical history, suggesting that the intervention was successful regardless of previous history of preterm birth. All women in the pessary group reported vaginal discharge after the pessary was fitted, 14 per cent had the pessary repositioned while one woman had the pessary removed and replaced. Ninety-five per cent of the women in the pessary group reported that they would recommend the treatment to other women. The mechanism of the action of the pessary is unclear, with the change in uterocervical angle or support of the immunological barrier between the membranes and vagina flora being proposed, but without convincing evidence.

Goya M, Pratcorona L, Merced C, et al. Cervical pessary in pregnant women with a short cervix (PECEP): an open-label randomised controlled trial. *Lancet* 2012: April 12.

HPV DNA test for cervical screening

Australia and New Zealand have widely available and effective cytological screening for cervical cancer, but this is not the case in all parts of the world. The authors of this Chinese study report that 85 per cent of cervical cancer is found in less-developed countries, with 14 per cent of new cases annually in China. These countries often lack the infrastructure and funding to implement a cytological screening program. This study included 13 000 women who all had the following evaluations: a self-collected HPV test; a physician-collected cervical HPV test; liquid-based cytology and visual inspection of the cervix with acetic acid. The self-collected HPV test had 86 per cent sensitivity and 81 per cent specificity for detecting CIN2+ and 86 per cent sensitivity and 80 per cent specificity for detecting CIN3+.

Visual inspection with acetic acid had lower sensitivity, but higher specificity, than the self-collected HPV test. Liquid-based cytology had lower sensitivity for detecting CIN2+ disease, similar sensitivity for detecting CIN3+, and higher specificity for detecting CIN2+ and CIN3+, compared to the self-collected HPV test. Physician-collected HPV testing was more sensitive for detecting CIN2+ and CIN3+, but similarly specific for detecting CIN2+ and CIN3+ than the self-collected HPV test. These results strongly suggest that adoption of self-collected HPV testing may provide an effective means of providing cervical screening to women in less-developed countries where a cytological screening program may not be available.

Zhao F, Lewkowitz AK, Chen F, et al. Pooled analysis of a self-sampling HPV DNA test as a cervical cancer primary screening method. *J Natl Cancer Inst* 2012. 104: 178-188.

Have you changed your address or email account recently?

Have you notified the College of these changes?

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Confinement: a Chinese perspective on the puerperium

Dr Tze Yoong Wong
RANZCOG Trainee

During your obstetric career you, or a colleague, may wonder why a Chinese woman is refusing to wash herself or to have an ice pack on her swollen perineum after childbirth. If so, then hopefully this article will cast a little light on the subject.

For centuries, following delivery of a child, Chinese women have been confined to the house for a month (hence the name confinement, also known as 'doing the month', in Chinese terminology: *zuo yue zi*), where they observe various rituals during the postpartum period. The traditional roots of confinement hark back to a time of high maternal and neonatal morbidity and mortality rates, when women and newborns were quarantined to their homes to protect them from contracting communicable diseases. Confinement usually starts on the day of the baby's birth and ends with the celebration of the baby's first month. Traditionally, during the confinement period, women are cared for by their mother or mother-in-law. In Asia, those who can afford it sometimes hire a 'confinement lady' who advises and helps them with this cultural practice.

The confinement rituals have been passed down from generation to generation and have their roots in the Chinese belief system of a person having both negative (yin) and positive (yang) properties – cold and hot, wind and fire and so forth – that are required to be perfectly balanced in order for them to be healthy. Chinese people believe that following childbirth a woman's yin and yang is imbalanced to the extent that her body is in a 'cold' phase (yin) due to the loss of blood and energy expended during labour. Therefore, the purpose of confinement is to ensure the future wellbeing of the woman by observing various proscriptive (avoiding yin) and prescriptive (restoring yang) rituals, so as to return her body back into a state of harmony. Adherence fluctuates depending on the importance placed on certain rituals by the woman herself or her immediate family (her own and her in-laws). Outlined here are the main rituals of confinement, but there are many more.

The washing of the woman's hair and body are prohibited within the month to avoid contact with cold water, which is said to cause 'wind' to enter the body through the joints or orifices that may cause asthma, arthritis or other severe aches and pains in the future. Over time, this ritual has been modified by some families to allow bathing with warm boiled water or water that has been boiled with ginger root or Chinese herbs, which are believed to have yang properties that help to dispel 'wind'. Some also avoid the proscription on washing their hair by using dry shampoos. However, most women have taken a more flexible approach to perineal care to reflect current medical thinking: they clean the incisions or tears with boiled water or antiseptic solutions to reduce the risk of infection.

Confinement more often than not also includes the prohibition on going outdoors for the entire month, as this too risks coming into contact with 'wind'. Moreover, regardless of the outside temperature, a postpartum woman tends to avoid exposure to 'wind' from air conditioning or fans. This also extends to women being wrapped in layers of clothing, wearing long-sleeved tops, socks and slippers.

Sexual intercourse is generally avoided during the confinement period as it is believed it could bring misfortune to the woman herself or her sexual partner, as the lochia is considered to be spiritually unclean. Some, however, observe abstinence from sexual intercourse on the basis that it gives time for tissue healing and guards against potential genital tract infections.

Food plays a major part of confinement; a yang (hot) diet is consumed to rebalance the yin (cold) forces and to purge the body of 'wind' that is believed to occur during labour. A 'hot' diet is also thought to promote blood circulation, strengthen the joints and aid the supply of breast milk. 'Hot' ingredients include chicken, pork, old ginger, sesame oil, traditional Chinese herbal wine, black vinegar and so forth, which are believed to give 'internal heat'. Moreover, these ingredients are considered to be nutritious so will boost a woman's energy levels and speed the recovery process. While herbal wine is often prescribed, there is a growing debate within the Chinese community as to whether this is advisable for nursing mothers or not as it is feared that the alcohol may pass to the child via the breast milk. Less controversially, 'hot' drinks such as ginger, red date and longan teas, are also prescribed as a means of restoring the depleted yang levels. Cold foods are, however, to be avoided, such as root vegetables, most fruits, some fish and shellfish. In this regard, 'cold' foods are those that are cold in nature, in other words where they grow or live in cold places (underground or in water), or those which are physically cold, for example, iced water.

The aforementioned rituals are thought to help women avoid ill health in their old age, because they are deemed to be susceptible to ailments during the postpartum period due to the body's pores being open to the elements after childbirth. Thus, they should avoid 'wind' and 'cold' elements and instead store up on 'hot' element to rebalance the body's yin and yang. In modern times, some Chinese women argue that many of these rituals have their roots in another time when there was a lack of hot running water and heating and, as such, no longer need to be adhered to. Rather, where they are observed it is often only as a mark of respect for their elders' wishes and customs.

Irrespective of individual motivations or whether you and I as modern medical practitioners think that these are outmoded and illogical ideas, these rituals hold cultural significance for the Chinese community. Therefore, the Australasian medical profession should be broadly aware of these rituals in order to provide a culturally responsive service that treats Chinese

patients and their families with respect and understanding. This is especially so given the growing Chinese population within Australasia. In Australia and New Zealand, Chinese is the largest Asian ethnic group. In the last census carried out in New Zealand (2006), 147 570 people identified themselves as Chinese (3.66 per cent of total population), which represents a 40.5 per cent increase from the previous census (2001). The Australian census for the same time period indicates that Chinese people account for over 3.37 per cent (669 890) of its population.

Medical practitioners and administrators in Australasia have a strong record of being sensitive to the requirements of the multicultural community they serve. In explaining the rituals and the belief system that underpin confinement, it is hoped that it will provide the Australasian medical community with a greater insight into the needs and values of those members of the Chinese community who wish to follow this tradition. An awareness of the reasons why a postpartum Chinese woman wishes not to wash, for instance, may prevent medical professionals from being culturally insensitive to such a patient, whether during a hospital stay or at a postnatal visit. Furthermore, there are implications for the manner in which some Chinese women may like to be treated, such as having the ability to control the air conditioning in the postnatal room, which could enhance their postnatal recovery experience in Australasian hospitals without violating cultural beliefs. There is also potential scope for bolstering the health outcomes of these women through the delivery of culturally congruent care, and reducing any feelings of isolation that may arise from having their motivations misunderstood, during the life events of childbirth and puerperium.

Ultimately, it may also provide you with some answers if you hear the sounds of consternation coming from a colleague when they are caring for a Chinese female patient who refuses to wash or to have an ice pack after childbirth.

References are available from the author upon request.

Q&a

Q&a attempts to provide balanced answers to those curly-yet-common questions in obstetrics and gynaecology for the broader *O&G Magazine* readership including Diplomates, Trainees, medical students and other health professionals.

Q *What do you do when faced with unexpected ovarian pathology at laparotomy for benign indication in a premenopausal woman?*

Dr Helen Paterson
BM, FRANZCOG, MMedSci
Senior Lecturer
University of Otago

Dr Kate Coffey
MBBS, MA, Pg Cert ClinEd
Honorary Clinical Lecturer
University of Otago

a During a career in obstetrics and gynaecology, unexpected pathology is likely to be encountered intra-operatively.[1,2] When these findings affect the genital tract, it can be difficult to know how best to proceed – particularly in the young or premenopausal woman who may not have completed, or even commenced, her reproductive life.

Many of us have been in the uncomfortable position of performing surgery for an ectopic, only to find that the contralateral tube is also abnormal; or, in a patient with a compromised tube, that the new problem is unexpectedly on the 'good' side. With ovarian pathology at hysterectomy for a benign indication, the issue is less thorny. As pregnancy will no longer be possible, dealing with an unexpected finding appears more straightforward. Guidelines and clinical practice with reference to elective bilateral salpingo-oophorectomy (BSO) at hysterectomy have changed significantly in recent years, but perhaps our attitudes to this small endocrine organ have not moved with the times?

As medical students, we probably all heard countless iterations of 'the ovary discussion'. 'They're going to stop working soon anyhow, so while we're in there we may as well…' It was common to routinely remove healthy ovaries at the time of a hysterectomy performed for benign indications (most commonly menorrhagia or dysfunctional uterine bleeding during the climacteric) in relatively young women. The rationale was that over 45 years of age the ovaries were nearing their 'use by' date and, left in situ, posed a one in 80 lifetime risk of ovarian cancer.

The American Congress of Obstetricians and Gynecologists recommended a conservative approach to elective BSO at hysterectomy in 2008[4]; our own College followed suit in 2009.[5] But it seems a change in practice may be difficult to achieve. Contrary to the College guideline, in 2011, 50 per cent of surveyed O and G specialists and registrars in West Sydney still recommended routine elective oophorectomy at the time of hysterectomy for women aged 55 and over; perhaps because fewer than half of respondents (44 per cent) were aware of the contents of the College statement.[6]

If we accept that best practice is to leave the ovaries in situ if they are healthy, what are the implications for ovaries that might be diseased? Ms J was a 39-year-old with menorrhagia and uterine fibroids. Medical management and trial of intrauterine system failed to control her symptoms. After consultation with a gynaecologist (who was aware of the College guideline) she opted for a total abdominal hysterectomy with ovarian conservation. Unexpectedly, at laparotomy her right ovary appeared grossly abnormal; enlarged to 8cm in diameter, it had a rubbery consistency. What to do?

Where malignancy is suspected the situation appears relatively straightforward and most gynaecologists probably wouldn't think twice about removing the ovary, unless the patient specifically desired future fertility. However, even where malignancy is suspected there may be good clinical reasons to delay definitive management. Tumour markers and imaging may confirm the diagnosis; a staging procedure may be the optimal management; or it may be a situation where dissemination of malignant cells is likely if removal is attempted.[3] First, do no harm.

Returning to our patient, when the grossly enlarged ovary was noted – 'I didn't know what it was, but I knew I had never seen anything like it' – the surgeon felt that a unilateral salpingo-oophorectomy was the best option. There was no obvious cyst to remove and frozen section was not available without prior arrangement. Histology showed massive ovarian oedema, a rare benign condition ascribed to recurrent partial torsion where lymphatic and venous drainage are impaired, but the arterial supply is preserved, protecting the ovary from necrosis.[7]

Could we have left the ovary? Surprisingly, even in the case of ovarian torsion with frank necrosis a conservative approach is now recommended, particularly in children and adolescents, as rates of ovarian recovery after torsion with prolonged ischaemia are good.[3] Is the balance of risk and benefit different in the perimenopausal woman? In our case, the surgeon and patient had discussed ovarian conservation pre-operatively. The patient was in a same-sex relationship and not planning to have children. She had no family history of ovarian cancer and was happy to 'keep' her ovaries based

on a discussion about the merits of endogenous hormone production (bone, cardiovascular, libido). She understood and accepted the small lifetime risk of ovarian cancer. However, many of us have encountered patients who are not ambivalent about oophorectomy.

One might wonder what all of the fuss is about. Ovaries do not feature frequently as a topic of conversation at dinner parties. They are socially and literally invisible other than at laparotomy or laparoscopy (and, until recently, when we did see them we would often whip them out). Fortunately, as a profession, we have moved on from the days when 'ovarieotomy', or Battey's Operation, was performed for 'menstrual madness, neurasthenia, nymphomania, masturbation and "all cases of insanity"'.[8] Historical interest aside, is there any reason to worry about oophorectomy? We have all come across patients who do.

Perhaps the only way to understand the potential importance of a woman's ovaries to her is to think about men; specifically, the male gonad. Unlike the ovary, homage is regularly paid to the testis in common parlance. Testes are used as a metaphor for courage ('that took balls'), as disparagement ('bollocks to that'), and as an expression of disbelief ('balls!'). So let us imagine a clinical scenario: your husband, brother or son goes into hospital for a relatively simple urological procedure; let's say a transurethral resection of the prostate (TURP). Intra-operatively one of the surgeons becomes suspicious that the patient's testicle is pathologically enlarged and feels a bit rubbery. Based on his concern, he removes the testicle without consent. Would we expect the patient to react with equanimity? Are we perhaps underestimating the impact of oophorectomy on our patients due to our historical practice? Our recommendations: read C-Gyn 25[5], remember that a 'use by' and a 'best before' date are different[9], and the next time you see an ovary, consider leaving it right where it is.

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RANZCOG members are invited to submit questions, tips or interesting cases to *Q&a*.
Please send entries to *Q&a* @ *O&G Magazine* via:
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Do you have a RACOG Fellow's gown that you no longer need?

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- The gowns can be upgraded to a RANZCOG gown with the addition of silver braid.
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Any enquiries please contact:
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Legal implications of fatigue

Dr Robert Norelli
FRANZCOG

In the medico-legal arena, fatigue is more than just feeling tired or drowsy: it affects performance, which provides the foundation for a civil claim for damages and, arguably, might become the basis of a criminal charge.

Not many years ago, clinicians took pride in the ability to work 60–80 hours a week without any noticeable incidence of adverse outcomes. Some of us are still making such a claim and with good reason, as such claims are usually true. The sentinel change is not the clinical outcomes, but rather society's perspective towards medical outcomes measurement and fatigue-management issues. Any doubts regarding this shift in societal perspective should be quickly dispelled by the reminder that the State of Queensland sentenced a technically competent surgeon to seven years in prison for the statutory crime of failing to use reasonable care while undertaking to administer surgical or medical treatment. Now consider the wording of the 2004 Occupational Health & Safety Act, which leaves little room for interpretation. Section 21(1) Employer's duty:

- to provide and maintain, so far as reasonably practicable, a working environment that is safe and without risk to health.

Section 25 provides employees duties to take care of their own health and safety and the safety of others. Section 25 says that while at work, an employee must:

- take reasonable care for his or her own health and safety;
- take reasonable care for the health and safety of persons who may be affected by the employee's acts or omissions at a workplace; and
- co-operate with his or her employer with respect to any action taken by the employer to comply with a requirement imposed by or under this Act or the regulations.

If you think you are immune to these regulations because you are self-employed, or functioning as a contractor, Section 24 says:

- a self-employed person must ensure, so far as is reasonably practicable, that persons are not exposed to risks to their health or safety arising from the conduct of the undertaking of the self-employed person.

If you are an unpaid volunteer, Section 32 outlines your duty not to recklessly endanger persons at workplaces. A person who, without lawful excuse, recklessly engages in conduct that places or may place another person who is at a workplace in danger of serious injury is guilty of an indictable offence and liable to:

- in the case of a natural person, a term of imprisonment not exceeding five years, or a fine not exceeding 1800 penalty units, or both; and
- in the case of a body corporate, a fine not exceeding 9000 penalty units.

There exists a combination of case law precedent and legislated regulations that directly affects every workplace in Australia. I can describe the response taken by Queensland Health: 'When a medical practitioner engaged by Queensland Health is required by Queensland Health to continue working due to operational requirements, the medical practitioner is or may become fatigued. Legal assistance, representation and indemnity are to be provided by Queensland Health at the request of the practitioner, when the incident subject to the claim would not have, on the balance of probabilities, occurred but for the fatigue. Written advice from an agreed independent fatigue management expert may be used to assess whether fatigue existed.'

Corporate administrators will insist that this means there is absolutely nothing to be worried about, as the fatigued clinician is covered by indemnity insurance. These same administrators do not want to talk about the possibility that the clinician might become excluded from coverage. Clause 7.3 states that a medical practitioner is not to be entitled to indemnity from a claim when:

- The medical practitioner's conduct that is the subject of the claim has been proven, to the satisfaction of Queensland Health, to constitute 'wilful neglect'.
- The medical practitioner has been convicted of a criminal offence arising from the conduct that is the subject of the claim (except where the conviction has arisen out of an incident subject to section 7.6).

This seems as though the clinician is truly indemnified, as long as any fatigue is 'due to operational requirements', even though nobody seems to have defined what constitutes operational requirements. Assume for a moment that this employer might want an escape clause in order to distance themselves from any perceived malpractice event in the media. Such an escape clause would easily be found in the term 'wilful neglect'. Wilful neglect might be defined as an individual's failure to abide by the rules, regulations, policies, procedures, guidelines and/or protocols relating to the mitigation of fatigue risk. After all, an employee's obligation to follow the policies and procedures of the employer is clearly agreed by the contract of employment. But at the time of this writing, Queensland Health references 811 pages of supporting documents pertaining to workplace fatigue. If there is a violation any one of those 811 pages, the employee might be considered to be committing wilful neglect. Remember, most of these documents are coming from the same source that said doctors could mitigate fatigue by drinking six cups of coffee while working fatigued.

Introduced on 1 July 2010, AHPRA has enacted a mandatory reporting obligation:

- Section 140 of the National Law requires that a registered health practitioner must notify the Board if, in the course of practising their profession, they form a reasonable belief that another registered health practitioner has behaved in a way that constitutes 'notifiable conduct'.

Notifiable conduct is defined as when a practitioner has:

1. practised the profession while intoxicated by alcohol or drugs;
2. engaged in sexual misconduct in connection with their profession;
3. placed the public at risk of substantial harm in their practice because they have an impairment; or
4. placed the public at risk of harm during their practice because of a significant departure from professional standards.

Could it be possible that working while fatigued is a deviation from professional standards? In order to address this question, we must

Table 1. National Code of Practice – Hours of Work, Shiftwork and Rostering for Hospital Doctors (AMA).

Lower risk	Significant risk	Higher risk
Less than 50 hours worked No more than 10 consecutive hours in any one period Scheduled shift hours worked Three or more short breaks taken during shift Little or no overtime Rostered for on-call less than 3 days in 7 days No night shift or extended hours into night shift	50 to 70 hours worked Up to 14 consecutive hours in any one period Scheduled shift plus part of next shift worked One or two short breaks taken during shift More than 10 hours overtime Rostered for on-call duty three days or more in a seven-day period At least two night shifts or extended hours into night shift	More than 70 hours worked 14 or more consecutive hours worked at least twice A full shift cycle worked of at least 24 hours. No short breaks taken during shift More than 20 hours overtime Rostered on-call continuously for more than a seven-day period At least three night shifts or extended hours into night shift

explore the relevant standards from a variety of professional bodies that have impact upon our practices. Starting with the Australia Medical Association (AMA) guidelines regarding fatigue (see Table 1), I submit that relatively few of us are consistently in the left-side column of 'lower risk'. Most of us are routinely (multiple times per month) working in the centre column of 'significant risk'. I will publically admit to having worked in the right-side column of 'higher risk' at least ten or 20 times per year, pretty much every year for the last 20 years. The primary issue is that society will no longer accept this behaviour as an explanation for any fatigue-related error.

Referring to the RANZCOG College statement (July 2009), 'Individual practitioners and Departments are also encouraged to familiarise themselves with the AMA's National Code of Practice – Hours of Work, Shiftwork and Rostering for Hospital Doctors'. All of the medical colleges in Australia have guidelines that are either in agreement with the AMA or are more restrictive, in an effort to ensure patient safety.

It is noteworthy to look at other, non-medical professions in order to establish the concept of professional standards. The Australia Marine Pilots Association, supervising the moving of commercial cargo ships into and out of Australia's harbours, has a definitive program for avoiding fatigue at the workplace. The following list of workplace standards is somewhat extensive, but they have delineated solutions to fatigue-related issues facing us in the medical arena.

- A period of marine pilotage duties shall be preceded by a rest period, at home or the pilot's place of residence, of at least:
  (a) nine consecutive hours embracing the hours between 2200 and 0600 local time; or
  (b) 12 consecutive hours.
- A period of marine pilotage duties shall not exceed 12 hours in any 24 consecutive hours.
- A marine pilot shall not be assigned to a ship where it is anticipated that the movement will be of a duration such that the pilot will be required to perform marine pilotage duties for a period of duty of more than 12 hours.
- Where a pilotage act has commenced...and the movement is delayed for reasons beyond the pilot's control the period of pilotage duty may be extended beyond 12 hours.
- Where extensions have been made...the pilot shall receive a rest period of 12 hours plus four hours for each hour or part thereof that the pilot's period of duty exceeds 12 hours.
- Where extensions have been made, the period of marine pilotage duties shall not exceed 16 hours.
- Where a pilot is required to perform a marine pilotage act or acts, a minimum of four hours marine pilotage duties is recorded irrespective of the actual hours worked.
- A marine pilot shall not be required to perform marine pilotage duties in excess of seven consecutive days without an uninterrupted rest period of not less than 24 hours.
- A marine pilot shall not be required to perform marine pilotage duties in excess of 120 hours in any three-week period.
- Where a pilot is on standby, a minimum of four hours marine pilotage duties is recorded irrespective of the actual hours worked.
- A marine pilot roster period shall be preceded by a rest period of not less than two days for each seven days worked in the preceding roster period.
- A marine pilot shall not be rostered on duty for more than 15 consecutive days.
- A marine pilot shall not perform pilotage acts on more than 200 days per annum.
- All marine pilots to whom this fatigue management plan applies shall keep a log of the hours worked and shall inform their employers of their rest requirements.
- The limitations on hours may be exceeded in cases of emergency and in all circumstances where the safety of life is concerned.

One of the most amazing aspects of this fatigue policy is that it was first presented in 1978!

In the USA, the Federal Aviation Administration (FAA) is attempting to avoid fatigue in the cockpit. A summary of the FAA limitation on actual flying hours (not hours of work time) is that a crewmember must not exceed total flying time maximum of: 15-hour duty-day, with eight hours' rest between required work periods; 30 hours in any seven consecutive days; 100 hours in any calendar month; and 1000 hours in any calendar year.

The FAA regulations go on to state that there must be pre-flight rest for scheduled flight during the 24 hours preceding the completion of any flight segment:

- Nine consecutive of hours of rest for less than eight hours of scheduled flight time;
- Ten hours of rest for eight hours or more, but less than nine hours, of scheduled flight time; or
- 11 hours of rest for nine hours or more scheduled flight time.

Considering airline pilots and marine pilots have developed duty-day limitations that have been approved or mandated by the government, we can assume these limitations represent the gold standard of human endurance in potentially dangerous occupations. It is only logical for doctors to acknowledge the comparison.

Another source of authority regarding fatigue management, especially significant to the plaintiff's solicitor or to the prosecution, would be the previously mentioned fatigue management experts. Prof

Drew Dawson is the Director of the Centre for Sleep Research at the University of South Australia. This Centre is within the School of Psychology. Prof Dawson's group has generated a variety of intriguing and potentially meaningful experimental results. As an example, an article titled Fatigue, Alcohol and Performance Impairment, published in 1997, indicated that each hour of wakefulness is comparable to an accumulation of 0.004 rise in blood alcohol levels. After 14 hours of wakefulness, there was an impairment of the subjects' motor skills performance equivalent to a blood alcohol level of 0.056. This means that fatigue can cause deterioration in motor function that would preclude the driving of an automobile anywhere in Australia, if it were induced by alcohol.

As a corollary to fatigue-verses-alcohol in loss of motor function, research demonstrates that perhaps the first human trait to be lost to fatigue is 'judgement'. So after a long night on-call, when your supervisor asks if you are feeling well enough to finish the day of scheduled clinics or the theatre list, choose your answer wisely. If you have been awake for 16 hours or more, the only appropriate answer to be given to such a question is: 'Don't ask me, I am too fatigued to judge.' Once again, the effect of fatigue might be worse than having a shot of spirits with breakfast. This emphasises that the total number of hours awake (without a period of adequate sleep) is more important than the number of hours slept during the last sleep period.

One of the complexities in requesting evidence-based medicine before important decision-making is that the evidence is often contrary to our previously held biases and beliefs. Consider a US military opinion paper titled Stimulant Use in Extended Flight Operations. This study concluded: 'In light of their value to mission accomplishment – especially in the absence of demonstrable negative effects – the ban on ampethetamines should be rescinded.' This was followed in 2000 by Performance Maintenance During Continuous Flight Operations: A Guide For Flight Surgeons. The US military differentiated between the concepts of 'continuous operations' versus 'sustained operations'. Continuous operations: extending over 24 hours at a 'normal' rate, not necessarily longer hours per individual; workers are relieved at the end of a shift and return later; the individual may work different hours that may conflict with the circadian rhythm; and sleep may be intermittent, interrupted and un-restorative. In contrast, sustained operations: involve individual continuous performance longer than 24 hours; work is continued until a goal is reached; and sleep deprivation is common.

This concept directly relates to a hospital. Although the operation of a hospital is continuous, the individual surgeon must have the opportunity to obtain necessary rest. However, when on-call for a three- or four-day weekend, the individual's performance is converted to a condition of sustained operations. Surprisingly, the directive to flight surgeons is that 'during sustained operations, an intermittent low-dose regimen of amphetamines has the capability of maintaining aviator performance yet avoiding undesired medication effects'. Perhaps the interpretation of this evidence is that all hospitals should be dispensing amphetamines to surgeons who are working fatigued. Conversely, the alternative is to limit the surgeons' duty-day to 16 hours as the only mechanism to guarantee an avoidance of fatigue.

In conclusion, there are five major points to be considered in any rational approach to fatigue management in your workplace:

1. Society, by virtue of contemporary legislation, is intolerant to errors resultant from fatigue. It no longer matters whatever the individual surgeon thinks about the time-on-duty verses their capacity to work a little bit longer. It doesn't matter that you have been working like this for 20 years without a problem. It is not that your endurance has changed. It is the rules of the game that have changed.
2. There is a consensus of opinion, being expressed by our licensing body, our professional colleges, comparable non-medical professions and the scientific research investigators that an eight- to ten-hour day is a normal work day; a 12-hour day is acceptable; and a 16-hour day is the absolute maximum that can be defended. Any performance of duties after a 16-hour duty-day can only be justified by offering compelling proof of an emergency. With the combined wisdom of the entire western world on the record stating that a 16-hour day is the maximum allowed, how can we doctors possible justify a 48- or 72- or 96-hour roster of scheduled on-call time?
3. The objective, both legally and ethically, is not a pursuit of a policy that defines how work will be performed by a fatigued doctor; the objective is to deny the fatigued doctor access to work. Exceptions can be made for natural disasters and poly-traumas from accidents, but one cannot work fatigued simply because the hospital administration uses the term 'operational requirement' (without providing an adequate definition). Since the on-call roster is published in advance, you have no option to say 'I didn't know'. Our opinions on this socially important matter must be heard now, when we are well rested. Don't ask my opinion during the crisis, as my judgement is the first to go.
4. Any bad outcome, whether real or imagined, cannot be defended when fatigue is a factor (excepting true emergencies). Working while fatigued will generate an increasing volume of complaints from the patient population and your co-workers in the hospital, ostensibly because you are 'rude' or 'short-tempered', when in fact you are merely fatigued. You are at risk of being in violation of your hospital's policies and owing to this wilful neglect you can loose your indemnity. You might become the defendant in a civil liability suit that has little chance of being defended, as your rostered hours on-duty and your presence in the theatre are well recorded. Although none of us wishes to acknowledge this potential reality, you might be found guilty of a statutory crime and be sentenced to prison. Queensland prosecutors have recently proven that they are willing to use a 150-year-old law to put a surgeon in prison for seven years. Imagine what they can do with these new laws.
5. As an experienced doctor, you are one of the very few people who simply cannot claim that you didn't understand the circumstances surrounding fatigue. We know the physiology of fatigue well. And, after reading this article, you also understand the legal implications. You are no longer in a position of plausible deniability. In short, the only explanation you can offer in regards to a fatigue related mal-occurrence is 'I allowed this bad thing to happen'.

References are available from the author upon request.

Criminal Code 1899 (Queensland) Reprinted as in force on 6 December 2011
Chapter 27 Section 288: Duty of persons doing dangerous acts
It is the duty of every person who, except in a case of necessity, undertakes to administer surgical or medical treatment to any other person, or to do any other lawful act which is or may be dangerous to human life or health, to have reasonable skill and to use reasonable care in doing such act, and the person is held to have caused any consequences that result to the life or health of any person by reason of any omission to observe or perform that duty.

College Statements update
March 2012

Louise Farrell
FRANZCOG
Chair, Women's Health Committee

The Women's Health Committee (WHC) re-issued the following statements in November 2011 and March 2012, which were subsequently endorsed by Council. College statements can be viewed on the College website.

From 2011
- Policy Statement on Shared Maternity Care Obstetric Patients in Australia (WPI 9)
- Guidelines for locum positions in specialist obstetric and gynaecological practice in Australia and New Zealand (WPI 12)
- Home Births (C-Obs 2)
- Management of the Menopause (C-Gyn 9)
- Management of the Menopause after Breast Cancer (C-Gyn 15)
- Diagnosis of Gestational Diabetes Mellitus (C-Obs 7)
- Placenta Accreta (C-Obs 20)
- Use of Cervical Fetal Fibronectin and Phosphorylated Insulin-Like Growth Factor Binding Protein 1 as Screening Tests for Preterm Birth (C-Obs 26)
- Women and Smoking (C-Gen 5)
- Guidelines for the use of Rh (D) Immunoglobulin (Anti-D) in obstetrics in Australia (C-Obs 6)
- Re-entry guidelines following a prolonged period of absence from practice and retraining programs for Fellows (WPI 13)

New College Statements
The following new statements were endorsed by RANZCOG Council and Board in March 2012 and November 2011:
- The Personally Controlled Electronic Health Record (WPI 22)
- Perinatal Anxiety and Depression (C-Gen 18)
- Cultural Competency (WPI 20)
- Antibiotic Prophylaxis for Obstetric and Gynaecological Surgery (C-Gen 17)
- Influenza Vaccination for Pregnant Women (C-Obs 45)
- Guidelines for Scanning of Live Subjects for Teaching Purposes (WPI 21)

Revised College Statements
The following statements were re-endorsed by RANZCOG Council and Board in March 2012 with significant amendments:
- RANZCOG Guideline: Suitability Criteria for Models of Care and Indications for Referral within & between Models of Care (C-Obs 30)
- Investigation of Intermenstrual and Post-Coital Bleeding (C-Gyn 6)
- Tamoxifen and the Endometrium (C-Gyn 12)
- Termination of Pregnancy (C-Gyn 17)
- Guidelines for the appointment of O&Gs to Specialist Positions in Aust & NZ (WPI 17)

The following statements were re-endorsed by RANZCOG Council and Board in March 2012 with minor or no amendments:
- Timing of Elective Caesarean Section at Term (C-Obs 23)
- Use of Prostaglandins for Cervical Ripening prior to the Induction of Labour (C-Obs 22)
- RANZCOG Standards in Maternity Care in Australia and New Zealand (C-Obs 41)
- Position Statement on the Provision of Obstetric Anaesthesia and Analgesia Services (WPI 14)
- Umbilical Cord Blood Banking (C-Obs 18)
- Position Statement on the Appropriate Use of Diagnostic Ultrasound (C-Gen 10)
- Use of the Veres needle to obtain pneumoperitoneum prior to laparoscopy (C-Gyn 7)

New College Statements under development
- Routine testing of serum TSH level in pregnant women
- Vasa Previa
- Illicit Drugs in Pregnancy
- Oral Contraceptive Pill

RANZCOG Women's Health Services Department
Should you have any queries for the Women's Health Committee or WHS, please use the following contact details:
Ms Shamila Kumar
(t) +61 3 9412 2920
(e) skumar@ranzcog.edu.au.

College website
College statements
Can be viewed at: http://www.ranzcog.edu.au/womens-health/statements-a-guidelines/college-statements.html . Should you have any difficulties with any documents from the webpage, please contact Shamila Kumar at the College (t) +61 3 9412 2920 (e) skumar@ranzcog.edu.au .

Resources for Fellows
This section includes local and international guidelines and articles of interest such as links to new titles on ACOG Committee Opinions and Practice Bulletins, SOGC Clinical Guidelines, National Institute of Clinical Excellence (NICE) guidelines and Department of Health and Ageing reports. Access at: http://www.ranzcog.edu.au/members-services/fellows/resources-for-fellows.html .

WPI 22 The Personally Controlled Electronic Health Record (PCEHR)

1st Endorsed: Mar 2012
Current: Mar 2012
Review: Mar 2015

The Personally Controlled Electronic Health Record (PCEHR) is an Australian Government program, under the governance of the Department of Health and Aging, implemented by the National eHealth Transition Authority (NeHTA). The system is scheduled to go live 1 July 2012.

The PCEHR is a form of a shared electronic health record. Standardised information about health care events, such as hospital admissions, discharge summaries, referral letters or pathology may be included in the record. The PECHR contains demographic information, in addition to clinical documents uploaded by healthcare providers or other authorised users, such as discharge summaries, pathology results, referral letters and information added to the record by the patient. Automatic feeds of information from the MBS, PBS, ACIR, and AODR repositories may be included.

Importantly, the content of the PCEHR is under the control of the individual patient who may choose which elements he or she wishes to include in the PCEHR and share with a specified health service.

The PCEHR is an opt-in system for both patients and providers. Patients are not required to have or use the PCEHR and may opt-out at any time. Health care providers are not under any duty or obligation to use the PCEHR. Once registered for the system, medical practitioners may choose to opt out for any or all patients or components of the system at any time.

Proposed Benefits of the PCEHR
The PCER may empower and encourage patients to take responsibility for their own health.
The PCEHR could provide practitioners with additional information and may be a mechanism for ongoing communication between doctors and patients in the management of their healthcare. The PCEHR may facilitate the management of transient or complex patients.

Concerns about PCEHR Implementation
There is limited data on the reliability and validity of the PCEHR. The PCEHR has practical clinical limitations for the treatment of the patient with respect to the content, accuracy and accessibility of the information. The medico-legal risks for medical practitioners and medical practices will be unknown until case law is developed as a result of actions. As with most medico-legal matters, the risk of exposure is low unless and until a patient experiences an adverse event. Shared electronic health records do not replace a medical practitioner's patient file and, if a medical practitioner relies on information sourced from a patient's shared electronic health record to make a clinical decision, diagnosis or recommendation to the patient, that information should be downloaded or printed from the shared electronic health record and incorporated into the practice's medical record.

Recommendation for Members and Affiliates
Limited public information is available on the functionality and governance of the PCEHR. Until such information becomes available, it is recommended that:

1. Medical practices and health care services establish individual practice protocols for the use of the PCEHR by July 2012. These protocols should include:
   - the way in which the medical practitioner will use shared electronic health records (eg, read only, or read and upload)
   - policies on when practice nurses and other allied health practitioners employed or contracted by the practice will use electronic health records
   - policies on when administrative and support staff are authorised to access shared electronic health records
   - the practice's policy and procedures regarding safety and confidentiality of electronic records
   - procedures for obtaining patient consent to use their shared electronic health record, and how this applies not only to the medical practitioner but all practice staff.
2. In the absence of further information, practitioners should exercise caution in accessing or contributing to the PCEHR.

Once further information becomes available, it is expected that the Australian Medical Association (AMA) will release a guide to the use of the PCEHR. At that point, RANZCOG may revise this statement.

WPI 20 Cultural Competency

1st Endorsed: Nov 2011
Current: Nov 2011
Review: Nov 2014

RANZCOG is an inclusive organisation of doctors from diverse backgrounds. Its membership is dedicated to caring for women and their families from an equally broad range of backgrounds. The College acknowledges in its Code of Ethical Practice (2002) the need for doctors to recognise and respect this diversity of ethnicity, religious, social and cultural values and beliefs. Cultural competency strives to underpin a reciprocal relationship between service provision and the meeting of cultural needs.

RANZCOG is an organization that places a high priority on cultural competency, and affirms a set of principles and policies that allow it to perform effectively in diverse circumstances. In addition it strives to educate, support and advise its members in these endeavours.

The principles that guide cultural competency are based on:

1. recognition of the importance of reciprocal trust between practitioner and patient
2. recognition that a patient's culture may influence their understanding, assimilation and acceptance of health information and behaviour
3. recognition that by giving patients from diverse backgrounds the ability to make informed choices, better outcomes can be achieved for the health service, the practitioners and patients.

The College encourages all fellows, members, and affiliates to embrace and develop cultural competency in their work.

Further reading

Waitangi Tribunal, 2011; The Treaty of Waitangi. Accessed: Sep 2011.
Medical Council of New Zealand, Aug 2006; Statement on Cultural Competence. Accessed: Sep 2011.
Commonwealth of Australia, 2011; National Anti-Discrimination Information Gateway - Australia. Accessed: Sep 2011.

References are available online.

For disclaimer, see below.

C-Obs 45 Influenza Vaccination during Pregnancy

1st Endorsed: Nov 2011
Current: Nov 2011
Review: Nov 2014

Influenza vaccination during pregnancy should be routine: safety is well established and both maternal and infant benefit is now proven with only 5 vaccination doses estimated to prevent one case of serious maternal or infant respiratory illness.

- Preventing influenza during pregnancy is an essential part of antenatal care because pregnant women are at an increased risk of serious illness due to influenza. Excess morbidity and mortality for pregnant women infected with influenza compared with non-pregnant women of similar age who are infected with influenza has been noted during pandemics as long ago as 1918, but drew public and professional attention most recently during 2009.
- The most effective strategy for preventing influenza in pregnant women is annual immunisation. Influenza vaccination is estimated to prevent 1 to 2 hospitalisations per 1000 women vaccinated during the second or third trimester.
- Influenza vaccination is recommended for all pregnant women regardless of gestation.
- Inactivated influenza vaccine is usually available from February each year in the Southern Hemisphere. Live attenuated influenza vaccination has not been licensed in Australia.
- Vaccination early in the season and regardless of gestational age is optimal, but unvaccinated pregnant women should be immunized at any time during influenza season as long as the vaccine supply lasts. Some maternal benefit is might accrue as early as 2 weeks after vaccination with research in pregnant women demonstrating seroconversion by 4 to 6 weeks after vaccination. Infection in the 3rd trimester of pregnancy appears to be the most dangerous for the pregnant woman.
- No study to date has shown an adverse consequence of inactivated influenza vaccine in pregnant women or their offspring.
- Active placental transfer of maternal antibodies makes influenza vaccine during pregnancy a highly effective measure to protect infants from influenza during the first 6 months of life.
- The Australian Government Department of Health and Aging strongly recommends vaccination for pregnant women (http://immunise.health.gov.au).
- RANZCOG strongly endorses routine vaccination of pregnant women against influenza.
- RANZCOG strongly endorses routine vaccination of obstetric and midwifery staff, both to protect these individuals as well as their families, closes contacts and patients.

References are available online.

Disclaimer

This College Statement is intended to provide general advice to Practitioners. The statement should never be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of each patient.

The statement has been prepared having regard to general circumstances. It is the responsibility of each Practitioner to have regard to the particular circumstances of each case, and the application of this statement in each case. In particular, clinical management must always be responsive to the needs of the individual patient and the particular circumstances of each case.

This College statement has been prepared having regard to the information available at the time of its preparation, and each Practitioner must have regard to relevant information, research or material which may have been published or become available subsequently.

Whilst the College endeavours to ensure that College statements are accurate and current at the time of their preparation, it takes no responsibility for matters arising from changed circumstances or information or material that may have become available after the date of the statements.

RANZCOG Research Foundation

Scholarships and Fellowships in 2012

Prof Jonathan Morris
Chair, Grants and Scholarships Committee

As in past years, the RANZCOG Research Foundation offered a number of research scholarships for application in 2011 for research commencing in 2012. The Foundation's selection process is closely modelled on that of the National Health and Medical Research Council, and each year an increasing number of highly competitive applications are received.

Three new awards were also available for application for the first time: the RANZCOG Fellows' Clinical Research Scholarship, ASGO International Travel Fellowship and ASGO National Travel Fellowship (not awarded this year). The RANZCOG Fellows' Clinical Research Scholarship was established using funds donated by the College to the Research Foundation, while the ASGO Travel Fellowships are funded by the Australian Society of Gynaecologic Oncologists (ASGO) and seek to facilitate links and the sharing of knowledge within the gynaecological oncology community.

Arthur Wilson Memorial Scholarship, 2012–2013

Recipient: Dr Clare Whitehead
Dr Whitehead is a RANZCOG Trainee and was awarded the scholarship for her project: Measuring Hypoxic-induced mRNA Transcripts in Maternal Blood to Identify the Hypoxic Growth Restricted Fetus. Fetal growth restriction is a major cause of stillbirth and current methods to monitor the wellbeing of a growth-restricted baby are sub-optimal. The project aims to develop a new method to monitor the wellbeing of the baby using a molecule in the mother's blood. Over the next two years blood samples from mothers carrying either growth restricted or well babies will be collected to develop this test. If successful, this test may reduce the number of babies lost due to fetal growth restriction.

Fotheringham Research Fellowship, 2012–2013

Recipient: Dr Phillip McChesney
Dr Phillip McChesney is a RANZCOG Fellow and CREI Trainee and was awarded the Fellowship for his project: A Randomised, Single Blind Controlled Study Assessing the Effect of Endometrial Injury on Live Birth Rate in Women Who are Undergoing an IVF/ICSI Cycle. The study aims to determine whether a single luteal phase biopsy influences the live birth rate in women under 40 years of age who have failed to conceive a clinical pregnancy, despite having undergone at least two embryo transfers of reasonable quality embryos.

Luke Proposch Perinatal Research Scholarship, 2012

Recipient: Mrs Hala Phipps
Mrs Phipps is a research midwife in obstetrics and was awarded the Luke Proposch perinatal Research Scholarship for her project: Persistent Occipito-Posterior: Outcomes following digital rotation (the POPOUT Study). This is a blinded multicentre RCT of manual rotation versus a 'sham' procedure, in 254 women with a baby in the posterior position during the second stage of labour. This world-first Australian-led trial has the potential to reduce the rate of operative delivery (forceps, suction cup or caesarean section) simply and effectively by correcting the baby's position and allowing for normal descent and a normal vaginal birth. This trial directly addresses one of the most important issues in modern management of birth: the increasing proportion of women who have a caesarean birth.

RANZCOG Fellows' Clinical Research Scholarship, 2012

Recipient: Dr Vivien Wong
Dr Wong is a RANZCOG Fellow and CU Trainee and was awarded the scholarship for her project – The Puborectalis Sling Study: a multicentre, randomised controlled study of pelvic organ prolapse repair using a novel method. The study will be conducted at seven sites within Australia over five years, to look at the effectiveness of a new surgical technique for repairing pelvic organ prolapse whereby a piece of synthetic mesh is inserted around the back passage to the pubic bone like a brace around the pelvic opening, to try and reduce the risk of prolapse reoccurring. 100 women will receive the new surgical technique on top of their standard operation and the other 100 women just their planned operation. The results of the two groups will be compared for recurrence of prolapse, as seen on ultrasound scan as well as clinically.

Taylor-Hammond Research Scholarship, 2012

Recipient: Dr Oliver Daly

Dr Daly is a post-Membership CU Trainee and was awarded the Taylor-Hammond Research Scholarship for his project: the Causes and Consequences of Obstetric-related Pelvic Floor Trauma. The study aims to investigate the incidence, risk factors, pelvic symptoms and concomitant pelvic floor muscle trauma associated with obstetric anal sphincter injury and the implementation of a standardised risk-prevention strategy. An analysis of first-time mothers with birth-related anal sphincter injury will include a 20-year review of the rates and risk factors; two-year study assessing pelvic floor symptoms and examination for prolapse and ultrasound; and pre- and post-implementation cohort study of a clinical practice guideline.

ASGO International Travelling Fellowship, 2012

Recipient: Dr Jegajeeva Rao

Dr Rao was awarded the inaugural ASGO International Travelling Fellowship for the purpose of a review of High Risk Human Papillomavirus DNA Testing as a Test of Cure in patients previously treated for cervical pre-invasive diseases at the Gynaecological Cancer Centre and Pre-invasive Disease and Colposcopy Unit at the Royal Hospital for Women, Sydney, New South Wales.

Beresford Buttery Travel Grant, 2012

Recipient: Dr Ryan Hodges

Dr Hodges was awarded the Beresford Buttery Travel Grant for the purpose of clinical and research work focusing on novel fetal surgical techniques, advanced fetal echocardiography and ultrasound for fetuses with congenital diaphragmatic hernia and intrauterine growth restriction at Fetal Treatment Centre, Department of Woman and Child, Katholieke Universiteit Leuven, Belgium. Dr Hodges is a RANZCOG Fellow and CMFM Trainee.

Brown Craig Travel Fellowship, 2012

Recipient: Dr Oliver Daly

Dr Daly was awarded the Brown Craig Travelling Fellowship to attend the Urogynaecology and Pelvic Floor Reconstruction Unit, Croydon University Hospital, UK, to review the practice and outcomes of the ten-year experience at the Croydon perineal clinic; gain experience with assessment of pelvic floor and bowel dysfunction related to obstetric anal sphincter injury; and observe the components of the education and skills training provided to staff within the centre for the management of obstetric anal sphincter injury.

Are you interested in donating items to the Historical Collections?

We welcome enquires regarding donations.

If you have any items that you believe might be of value to the Historical Collections and you would be interested in donating them, please see the instructions below:

- Compile a list of items with a brief description. For books, include author, title, publisher, place and date. For archival and personal papers, include details. For museum items, include a brief description and the history of how you acquired it and attach a photograph.
- Email or post the list to one of the Historical Collections staff at the College.
- Contact the staff by telephone if you wish to discuss any items.

We look forward to hearing from you and would be delighted to consider any items you may wish to donate.

Librarian: Di Horrigan	Tuesday 9am-5pm	ph: +61 3 9412 2927	email: dhorrigan@ranzcog.edu.au
Museum Curator: Gráinne Murphy	Monday 9am-5pm	ph: +61 3 9412 2927	email: gmurphy@ranzcog.edu.au
Archivist: Ros Winspear	Mon, Wed, Thu 9am-5pm	ph: +61 3 9412 2934	email: rwinspear@ranzcog.edu.au

RANZCOG Women's Health Award 2011

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists has been proud to present the RANZCOG Women's Health Award for the past seven years, to outstanding university students in O and G from medical schools across Australia, New Zealand, Papua New Guinea and Fiji. Committed to promoting O and G as an exciting and valuable career, the College anticipates that this award will help foster awareness of the specialty among medical students.

The RANZCOG Women's Health Award 2011, valued at AUD$500, was received by the following successful awardees:

- Alice Sawka, School of Paediatrics & Reproductive Health, University of Adelaide
- Daniel Chan, University of Auckland
- Philip Chia, School of Clinical Medicine, Australian National University
- Eashan Tambimuttu, Bond University
- Dustin Mattie, Faculty of Health Sciences, Flinders University
- Jessica Forbes, Griffith University
- Kaycee Hocking, School of Medicine, James Cook University
- Aaron Wong, School of Medicine, University of Melbourne
- Nicole Xin Hui, Department of Obstetrics & Gynaecology, Monash University
- Jennifer Anne Young, University of Newcastle
- Alice Burton, University of New South Wales
- Kenric Smith, University of Notre Dame
- Kathryn Grant, School of Medicine, Dunedin Medical School, University of Otago
- Pafilio Tangitau and Terrence Kee, University of Papua New Guinea
- Joseph Comben, University of Queensland
- Tania Pertot, University of Sydney
- Rebecca Hutchens, School of Women's and Infants' Health, University of Western Australia

College House public open days

College House has been accepted into the Open House Melbourne Program for 2012, and will be open to the public on Saturday 28 July and Sunday 29 July from 10am to 4.00pm. Guided tours will be provided by College staff, focusing on the architecture, decorative interiors and historical collections, including: the entrance foyer and CEO's office, Council Room, Museum, Frank Forster Library, the Atrium and the Surgeon's courtyard. Staff members and volunteers from Open House Melbourne will be present on the day.

Open House Melbourne is an initiative of the Committee for Melbourne's 'Future Focus Group,' which aims to enrich the general public's affinity with Melbourne, by encouraging people to explore and engage with the vast range of beautiful buildings in the city.

The first Open House Melbourne event was held in 2008, when the eight featured buildings attracted more than 30 000 visits. Last year the event ran for two days, with 59 buildings open and 65 000 visits recorded. The 2012 weekend will deliver a wider range of buildings, including College House, with a target of 100 buildings.

For further information about the event, contact Ros Winspear (rwinspear@ranzcog.edu.au).

News from the Historical Collections

We wish to thank the following Fellows and Friends who have kindly donated items as listed to the Historical Collections during the last six months:

Abell, Dr David (Vic)	FRACOG gown; obstetric instruments in case
Connon, Dr Aileen (SA)	FRACOG gown
Crowe, Dr Peter (NSW)	MRCOG case records
Giles, Prof Warwick (NSW)	MRCOG case records
Martin, Prof John (WA)	Personal papers
Newlinds, Dr John (NSW)	MRCOG case records
O'Malley, Dr Terence (NSW)	FRACOG gown; RCOG crystal goblet; medallion
Roche, Dr James (NSW)	Books; metal sculpture; historical papers
Sloss, Dr William (Vic)	FRACOG gown belonging to his father Dr W L Sloss
Stewart, Dr Ian (NSW)	Llewellyn-Jones papers
Tischler, Dr Erhard (NSW)	MRCOG case records

Donations to the Friends of the College Collection

We are grateful to the following people who have generously made financial donations to the Friends of the College Collection in the last six months amounting to a total of AUD$2350.

Campbell, Dr John M (Qld)
Crowe, Dr Peter (NSW)
Davy, Dr Margaret (SA)
Farrell, Dr Louise (WA)
Fraser, Prof Ian (NSW)
Howell, Dr Euan (Vic)
Howes, Dr and Mrs Sam (Vic)
Jalland, Dr Mark (Vic)
Officer, Dr Colin (Vic)
O'Loughlin, Dr John (SA)
Ross, Mr Ian (Vic)
Svigos, Dr John (SA)
Thevathasan, Dr Christine (Vic)
Wallace, Dr Gilbert (NSW)
Watson, Dr Roy (SA)

Researcher visits the College

Ms Judith Godden, a historian from Sydney, recently spent a week at College House researching for the book she is writing on the history of the Women's Hospital (Crown Street), Sydney. The main purpose of her visit was to refer to the MRCOG case histories held in the Archives Collection that were prepared at Crown Street, as well as related papers and books in the Collections. We were pleased to welcome Ms Godden to the College and to be able to assist with her research. We look forward with interest to seeing the finished work.

Corrections

O&G Magazine Vol 14 No 1 p58. Caption should have read: 'showing prominent numbers of RhD positive fetal cells'.
O&G Magazine Vol 13 No 4 p14. The article Shifting Paradigms contained incorrect information. The Policy for Planned Home Birth in SA 2007 has been implemented in two sites. The authors wish to thank Prof Jodie Dodd for alerting them to this error.

Staff news

New appointments

Rosalie Sirotic joined RANZCOG in April as a re-accreditation/Diploma support officer in the training services department. After completing her bachelor of business (marketing) degree, she spent the first two and a half years of her career at Australia Post, initially as an administration assistant for Post Logistics, most recently as a marketing assistant for Messenger Post Couriers.

Lauren Patten joined RANZCOG in February as a coordinator working on PROMPT implementation and for the Research Foundation. She brings to the role experience gained during five years spent with the General Practice Training Program in Melbourne, in the Medical Education Unit, organising registrar and supervisor training programs.

Lauren trained as an Enrolled Nurse and holds a Diploma in Social Science (Early Childhood). Her career to date has included working for Family Planning Victoria, Southern Cross Care and the Blood Bank.

Departures

Kate Bell left her role with the College in the New Zealand office to move to Melbourne. We wish her well with her future endeavours. **Jessica NcNeill** left RANZCOG in April to move back to her home town, Canberra. We wish her all the best.

Notice of Deceased Fellows

The College was saddened to learn of the death of the following Fellows:

Dr Richard Henley Picker, NSW, on 20 September 2010*
Emeritus Prof James Lawrence Wright, New Zealand, on 8 September 2011
Dr Struan Birrell Robertson, NSW, on 17 February 2012*
Dr Malcolm Bernard Stumer, QLD, on 2 March 2012
Dr David Charles Morton, NSW, on 6 March 2012*
Dr John Daniel Crowley, New Zealand, on 13 March 2012
Dr John Desmond Hehir, ACT, on 3 May 2012
Mr Robert Fyfe Zacharin, Vic, on 9 May 2012

An obituary appears on pages 77–80 of this issue of *O&G Magazine*.

Applications invited for RANZCOG Board of Examiners

Fellows and Diplomates of the College are invited to apply for membership of the RANZCOG Board of Examiners.

Examinations are an integral part of the College's services and examiners are pivotal in ensuring that the College runs high-quality examinations that are transparent, reliable, valid and fair. RANZCOG has only one 'panel of examiners', the Board of Examiners, from which come the Diploma, Membership and Subspecialty examiners for each relevant Written and Oral examination. The aim of having a combined Board of Examiners is to allow an exchange of knowledge between Diploma, Membership and Subspecialist examiners.

Fellows and Diplomates who are appointed to the RANZCOG Board of Examiners provide a pivotal service in the ongoing development and assessment of trainees in specialist, subspecialist and general practice obstetrics and gynaecology.

Duties

Examiners can utilise their expertise by being involved in the following activities:

- Developing questions for the Multiple Choice Question (MCQ) examinations and the Short Answer Question (SAQ) written examinations
- Developing cases for oral examinations
- Participating in standard setting activities
- Marking examination papers against established criteria
- Examining candidates at the Diploma, Membership or Subspecialty Oral Examinations

Additional information

Availability

All examiners appointed to the Board are expected to make themselves available for at least one examination activity per year.

Method of Application

To be considered for appointment, an application must be submitted to the Education & Assessment Committee. An application form is available on the College website http://www.ranzcog.edu.au/education-a-training/board-of-examiners.html. The completed application form, together with a current curriculum vitae should be emailed to kgilliam@ranzcog.edu.au or, alternatively, sent by mail to College House, 254–260 Albert Street, East Melbourne, VIC 3002.

Enquiries

Any questions regarding applications should be directed to Kate Gilliam, Education & Assessment Committee coordinator on +61 3 9412 2962 or kgilliam@ranzcog.edu.au .

Obituaries

Dr Richard Henly Picker
1943 – 2011

Richard Henly Picker was educated at Sydney Grammar School and graduated with Honours from Sydney University in 1967. His residency was at Royal North Shore Hospital (RNSH), and he was initially attracted to a career in surgery. With this plan, he became an anatomy demonstrator at Sydney University, where he gained an appreciation of 'in-depth anatomy', knowledge that was to be of great benefit later in diagnostic ultrasound.

He changed his plans for surgery, and trained as a registrar in O and G at Royal North Shore Hospital. His enthusiasm and positive attitude was infectious and with his (prematurely) grey hair he quickly gained the admiration of his patients, to a level envied by his older peers.

He gained his MRCOG in 1972, and took up a position in Poole, Dorset, but a medical illness forced him and his family to return to Australia prematurely. He became a Foundation Fellow of the Australian College in 1980, and was elevated to Fellowship of the RCOG in 1981.

Ultrasound was in its infancy as a diagnostic tool in O and G, and he quickly grabbed this opportunity. As a research Fellow at RNSH, he trained with Bill Garrett and George Kossoff at the Royal Hospital for Women, and then established Diagnostic Ultrasound at RNSH.

From here, he had 12 chapters and over 40 papers published, improving the diagnostic accuracy of fetal weight and maturity assessment. He was associated with the RNSH IVF program, and diagnosed its first pregnancy in 1982, unfortunately as an ectopic. He quickly adopted oocyte pickup using the vaginal approach as ways were sought to make IVF less invasive for the patient.

In the early days of IVF, there was some adverse publicity about using this technology to treat couples with infertility. As shown in the photo above, he responded, dressed as Santa Claus (no padding required) at the RNSH IVF children's Christmas party. The television exposure following this event was on every channel, and helped convince the community it was a normal medical procedure.

He is survived by his wife, Jane, his daughters, Brooke and Samantha, and his grandchildren, Madeleine and Imogen.

Emeritus Prof Douglas Saunders
FRANZCOG
Sydney

Dr Graham John Robards
1945 – 2011

Dr Graham John Robards practised as a general O and G in Manly for 30 years, including many years as head of department. He had a very large mixed practice and, although he was also a visiting medical officer at the 'SAN' Hospital, Royal North Shore Hospital, Mona Vale Hospital and, in the later years, at the Mater and North Shore Private Hospital, he retained interest and loyalty to the development of the Manly maternity unit.

In addition to running a very busy private practice, he was devoted to the public patients at Manly Hospital and fought to prevent the closure of Manly Hospital when this was threatened several times, being active politically in this regard. He was a tireless committee member of the Senior Medical Staff Council and represented Manly Hospital, and especially the Maternity Department, at the Northern Sydney Area Health Service Board level.

He was also an enthusiastic lobbyist for a new public state-of-the-art hospital at French's Forest on the Northern Beaches, the plans of which are now in an advanced stage.

Graham was successful in attaining, his MBA later in his career while also working full time and, on his retirement from duty as a visiting medical officer at Manly, became a medical administrator, commissioning a major expansion of Wyong Hospital on behalf of Northern Sydney and Central Coast Health Service.

He also learned to play the French horn aged 40, playing for many years for the Australian Doctor's Orchestra, and was a lay preacher at his church in Roseville. He lived on the 13th tee of the Kooindah Golf Estate and loved golf.

He travelled a lot and, while in Africa, developed a non-Hodgkins lymphoma, in March 2011, followed by heart failure. Graham died in his Central Coast home hours after being discharged from hospital in December 2011. He is survived by his wife, Adrienne, and their children, Tim and Alison.

Dr James Ferry
FRANZCOG
Sydney

John (Bryan) Greenwell
1924 – 2012

John (known as Bryan) Greenwell was born, in Leura NSW, to Harold and Sarah Greenwell on 11 October 1924. He was the youngest of four children and his father owned a pharmacy in Katoomba. He attended Katoomba Public School and he finished his education at Sydney Grammar School in 1940; the following year he commenced the study of medicine at Sydney University, graduating in 1946.

He did his junior and senior residency at St Vincent's Hospital and, after a short experience with general practice in Granville, declined the suggestion to join his brother who was a GP in Katoomba and took up a resident medical officer position at the Royal Hospital for Women in Paddington. After two years as an resident medical officer and registrar he was appointed medical administrator from 1950 until 1952, when he worked his passage to London as a ship's doctor. He studied at the Postgraduate School of O and G in London between 1953 and 1954, at which time he was successful in obtaining his membership of the RCOG. On his return to Sydney, in 1954, he was appointed as general medical superintendent of the Royal Hospital for Women.

Bryan was unusual in that he proposed to spend his medical career involved in the running of the Royal Hospital for Women, or the Royal as it was affectionately known. In 1956, Greenwell married Pauline McLure and they had two children. In 1964, he joined East Sydney Rotary Club and on his retirement, in 2007, he was the longest serving member of 43 years.

Bryan was far sighted and early in his time at the Royal was involved in the appointment of a staff specialist O and G, initially this was Bruce Dawson and then, subsequently, Ed Bosch. He became aware of the importance of highly qualified O and Gs in salaried positions within the hospital and was instrumental in the appointment of Ed Bosch as director of medical services, Col Fisher as staff O and G and the author as deputy general medical superintendent. He was elevated to the Fellowship of the RCOG in 1963.

He was deeply interested in hospital administration and, after completing a course in administration, was appointed a Fellow of the Royal Australian College of Medical Administrators in 1973. He was a Foundation Fellow of the RACOG and, until his retirement, was the representative of the College on the Australian Council in Healthcare Standards. During his tenure at the Royal he was intimately involved in change and the institution of interventions that are now accepted as normal. He was the first to admit husbands into the delivery ward and to encourage the rooming-in of infants with their mothers. He was closely involved in the establishment of epidural anaesthesia for women in labour and for the introduction of obstetric ultrasound. The Ultrasound Department at the Royal was the second in the world. He had performed the first exchange transfusion for Rhesus isoimmunisation in Australia, in 1949, and oversaw the development of intrauterine transfusions for severely Rhesus-affected infants in utero; the Royal was made the state centre for the management of severely affected pregnancies. He encouraged the development of neonatal paediatrics and the establishment of a Newborn Intensive Care Unit. Throughout his time at the Royal he attended patients in the outpatients department, did operating lists and managed his own private O and G practice within the hospital as well as lecturing to midwifery and medical students.

In association with the Benevolent Society of NSW, Bryan saw the development of the Royal Hospital for Women into various divisions and departments with the extension of expertise within all of these. He retired in 1987, after 38 years' service to the Royal. His later years were marred by increasing ill health and he was predeceased by Pauline. He died on 6 January 2012 and is survived by his children, Lisa and Robert, and three grandchildren.

Dr Stephen James Steigrad
FRANZCOG
Sydney

Dr Robert (Bob) Austin Kenihan ED
1923 – 2012

Robert (Bob) Austin Kenihan was born on 1 February 1923, the son of Dr Raphael Leo Kenihan, a family medical practitioner, in metropolitan Adelaide. He attended Rostrevor College for his secondary schooling before entering and graduating MBBS from the University of Adelaide Medical School in 1946. During this time, he excelled at sport gaining a University 'blue' in lacrosse as well as being very proficient in cricket, swimming and, later, golf.

After internship at the Royal Adelaide Hospital, he saw military service in the Royal Australian Army Medical Corps (RAAMC) as a member of the British Commonwealth Occupation Forces in Japan 1948–49. This was the beginning of his long association with the RAAMC as a serving member of the Citizen Military Forces in which he held senior positions in 3 Field Ambulance from1949–67. He was duly recognised with the award of the Efficiency Decoration and Clasp for his meritorious service.

After completing a scholarship year at St Mary's Hospital for Women and Children, Manchester, UK, in 1952, he gained his MRCOG in London in 1953, his FRCOG in 1970, and was a Foundation Fellow of RACOG in 1978. He served as the SA Members Representative, Australian Regional Council RCOG, from 1962–68 and was an examiner for the Diploma of Obstetrics in the 1970s.

He started private practice as a consultant O and G in Launceston in 1953, before returning to Adelaide in 1956, to enter into private practice in association with Sir Brian Swift. After working as an honorary clinical assistant at The Queen Elizabeth Hospital and the

Royal Adelaide Hospital, he went on to faithfully serve the Queen Victoria Hospital, and subsequently the Women's and Children's Hospital, with great distinction as an honorary O and G from 1956 to 1971 and then as a senior visiting medical specialist and head of Obstetric Unit from 1971 to 1988.

Bob continued his private practice until his retirement in 1989, regretfully due to ill health, with the immense gratitude of his patients and their families, including this author whose three children he safely delivered.

From 1992–96 he served as a medical-legal officer for the Women's and Children's Hospital and concluded his association as a Member of the Board of Directors in the late 1990s. In recognition of his dedicated service he was made an Emeritus O and G of the Women's and Children's Hospital.

Bob was a very private person, particularly with regard to his family. He married Mary Elizabeth Denny in 1949, and they had six children who blessed them with 16 grandchildren and great-grandchildren. It was with great pride and a sense of history when he learnt that one of his granddaughters had been accepted into the University of Adelaide Medical School.

In retirement, Bob continued with his hobbies of gardening, stamp collecting and being a handyman at his beloved 'Kenwest' in Port Noarlunga. He passed away on 3 February, after a long illness, lovingly cared for by his wife, Mary Elizabeth, and his family.

Dr Jack O'Loughlin AO, past President of RACOG, was a former student and long-time associate. He delivered the eulogy at Bob's funeral service and he was moved to say: 'He was consistent not only in his dealings with his colleagues, but also in his commitment to his patients – always compassionate, always professional. Robert Kenihan was a prince of physicians. He graced our profession like few others.'

A/Prof John Svigos AM
FRANZCOG
Adelaide

Dr David Charles Morton
1929 – 2012

Dr David Morton was born at Wauchope, New South Wales, on 9 May 1929. David's father was a distinguished school teacher, and the family moved frequently in the early years, but his secondary schooling was at Sydney Boys High. He excelled in tennis, matriculated with a maximum pass in the leaving certificate and began medicine at Sydney University in 1946, along with more than 700 others. His older brother and sister, Max and Marion, did medicine at Sydney before him and both were prosectors in anatomy. David's high marks in first year also took him into the prosectory – a family achievement that will probably never be equalled. David was an extremely gifted and conscientious student, but still found time to play hockey. The friends he made during those years remained close to him for the rest of his life. During his obstetric term at the Royal Hospital for Women he met, and later married in 1953, a midwife, Dorothy Ironside. David graduated high in the Honours list in 1952, spent three years at Royal Newcastle Hospital, and turned down offers of registrarships in Surgery and Medicine to go into general practice at Port Macquarie until 1964.

He left a very successful practice there to specialise in O and G; starting at the bottom again and moving with a growing family to Hobart, initially, then the Area Department at Oxford, UK, then Southampton, acquiring the MRCOG in 1966, before returning to begin specialist practice at Gosford on the NSW central coast in 1968. David was the first fully trained obstetrician on the Central Coast, and rapidly developed a very busy referral practice; no doubt aided by his extensive experience in general practice. He was the doyen of the specialty at Gosford Hospital, always actively involved in teaching, at which he was naturally gifted. He also found time to write articles on a wide range of subjects, including one on Barton's forceps on which he became a real expert. He was elevated to FRCOG in 1977; a Foundation Fellow of the Australian College in 1979, serving on State Reference committee for NSW; an active member of the Newcastle O and G Society; and was on the Board of the Hunter Postgraduate Medical Institute. He was an early adopter of the laparoscope and, as part of a College team to Manado in North Sulawesi in 1979, taught the local specialists how to carry out laparoscopy.

He later acquired the Diploma in Diagnostic Ultrasound, Dorothy became a qualified ultrasound radiographer and, with the late Dr Malcolm Catt, they developed a quality ultrasound facility serving the central coast as well as continuing a busy O and G practice, until David retired in 1996. From 1993, David and Dorothy were active members of the Australian Gynaecological Travelling Society, and David's thought-provoking scientific contributions were always a highlight. After the tragic and unexpected death of Dorothy, in 2005, David was blessed by a chance meeting with Robyn Ryan and she became a part of the wider Morton family. David was a talented landscape painter and woodworker. In spite of all David's professional achievements – about which he was always embarrassingly modest – his family was always the centre of his life and he was justifiably very proud of them all.

The way in which he coped with his final illness was typically David – he remained positive until the end, greatly enjoyed visits from friends, issued strict instructions that no one was allowed to be sorry for him and remained, as always, an inspiration to everyone around him. David died peacefully from pancreatic cancer at home in Gosford, on 6 March 2012, surrounded by his loving family. We were all privileged to have been part of his life.

Dr Alan Hewson
FRANZCOG
Newcastle, NSW

Dr Struan Birrell Robertson
1925 – 2012

Struan Birrell Robertson was born at home in Neutral Bay, Sydney, on 27 January 1925. His father, Ossian, a general practitioner with an obstetric interest, was the second Australian to obtain the MRCOG.

Struan attended Shore School in North Sydney and matriculated in 1942. During his time at Shore, he played rugby and rowed in the school's Senior Eight. He was vice-captain of the First Fifteen and a prefect in his final year. On leaving school he enlisted in the RAAF. After training at Narrandera and Uranquinty, he saw action in Bougainville and, later, in New Guinea.

Following his discharge from the RAAF, in 1946, Struan enrolled in Medicine at Sydney University. He took up rowing again and was a member of the University's Oxford and Cambridge Cup-winning eight, earning him a university sporting blue.

After graduation, in 1952, and a year's residency at Sydney Hospital, Struan took a job at the Women's Hospital, Crown Street. After three years' training, he travelled to the UK to obtain his MRCOG. On his return to Australia he joined his father in general practice, while attending Crown Street as clinical assistant. In 1962 he obtained full consultant status at Crown Street. This allowed him to expand his two special interests – infertility and the treatment of severe Rhesus disease.

The early 1960s was a time when issues of infertility were beginning to be addressed in a more scientific way, with hormone measurement becoming available and pharmacological means of inducing and supporting ovulation beginning to appear. Struan pioneered the use of donor artificial insemination to overcome that particular male infertility problem. He also published on culdoscopy, the technique being supplanted by laparoscopy from the 1970s.

At the 1967 FIGO Congress in Sydney, Struan gave a paper on Crown Street's experience with intrauterine transfusion for severely affected Rhesus pregnancies. Many women were able to see their infants born and survive as a result of this treatment and the improved neonatal care that was growing alongside the Rhesus treatment.

Retirement from practice saw him establish an oral history program within RANZCOG, interviewing many retired practitioners between 1997 and 2011. This valuable contribution was recognised by the College with the presentation of the Distinguished Service Medal in 2009, as shown in the photo above. His retirement also meant he was able to indulge more intensively in his other great love, sailing. A final tribute to Struan Robertson, something he initiated and then oversaw until his death, is the upcoming history of The Women's Hospital Crown Street, which is currently in preparation. Without Struan's constant efforts this important history would almost certainly not have got off the ground.

After a short period of failing health, Struan died peacefully at home on 17 February. He is survived by his children, Ian and Margaret, and grandchildren, Alistair, Laura, William and Duncan.

Dr Ian Stewart
FRANZCOG
Wagga Wagga, NSW

Asia Pacific Committee

Involved in a developing country?
We'd love to hear from you!

The APC is keen to be kept informed about activities and involvement of our Fellows in all developing countries, but particularly the Asia Pacific region. From this information we will be able to increase valuable networks and build a more comprehensive picture of the involvement of College Fellows in the region, either under the auspices of the College or via other avenues or personal connections you may have.

Please send one paragraph outlining details of any activities/projects/consultations you have been involved in over the past year or details of activities you will be involved in for the coming year to:

Carmel Walker
Coordinator Asia Pacific Services
(e) cwalker@ranzcog.edu.au

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Please review Product Information before prescribing.

PBS Information: This product is not listed on the PBS