



O&G

Magazine

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Controversies

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists



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From the President



Prof Michael Permezel
President

I commend to all Fellows the article by Immediate Past President Dr Rupert Sherwood in this issue of *O&G Magazine* (p12–14). Procedures are critically important to the training of a specialist obstetrician and gynaecologist. While 'competency-based training' is catchy phraseology for the educationalist, all who practice recognise the imperative of numbers. Competence comes from native abilities, quality of training and quantity of training. It is not until large numbers have been accomplished that actions become

intuitive and the trainee has an opportunity to experience the common nuances of surgery, while under supervision. Learning does not cease post-FRANZCOG, but occurs so much more readily if there has been a solid grounding while 'supervisory' assistance was available.

How much lower are the procedural training numbers than previously? Like most things in the College, this is hugely variable; however, few now travel overseas to boost training procedural numbers. Strategies to maximise procedural competence are discussed in Rupert's article, but focus must occur on both increasing procedural opportunities (for example, revised training program, reducing procedures performed by non-RANZCOG trainees) and maximising learning from the opportunities available (such as simulation, appropriate pre-vocational training).

Scientific meetings

2015 ASM in Brisbane

The most important forthcoming event on the College calendar is the RCOG World Congress 2015, Joint RCOG/RANZCOG Event to be held in Brisbane from 12–15 April 2015. A/Prof Ted Weaver heads the Organising Committee and with Dr Clare Boothroyd as Scientific Chair and RCOG colleagues, a great program has been prepared. I sincerely hope that all Fellows, Diplomates and Trainees will make an effort to attend this landmark event.

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FIGO 2021 – RANZCOG to bid

In 2021, it will be the turn of the FIGO Congress to rotate to the Asia Pacific region. Melbourne Convention & Exhibition Centre and Melbourne Convention Bureau are partnering with the College in a bid for the 2021 FIGO Congress. Competition is intense, with similar bids likely to come from Japan, Korea, Singapore and others. Australia has made the shortlist and will have the opportunity to impress when representatives of FIGO travel to Melbourne in February/March 2015 to conduct various site visits. The College is grateful to Prof Gab Kovacs, who has agreed to chair the Bid Committee. Gab will put together a team that will work to maximise the chances of succeeding in this great opportunity to showcase Australian and New Zealand obstetrics and gynaecology to a world audience.

‘The Royal Australasian College of Surgeons (RACS) has been quoted in the media as being concerned with the amount of reported out-of-pocket costs being incurred by patients in the healthcare sector...’

Women’s health

Consultation and Referral Guidelines from midwives to GPs or specialist obstetricians

Prof Sue Walker led a team to negotiate with the nominated representatives of the Australian College of Midwives (ACM) over the consultation and referral guidelines. RANZCOG had previously given feedback on the third edition of the ACM guidelines and recommended a number of changes. In a spirit of collegiality, both RANZCOG and ACM representatives were able to reach compromise positions on each of the remaining issues. Few from either profession will find the amended guideline to be perfect, but so much the better if there is an agreed standard for minimum thresholds for consultation and referral between the two key bodies. The consensus amendments have been passed by the ACM Board and went to the RANZCOG Board during November Council week.

Gestational diabetes mellitus

At the time of writing, the College is in the middle of the consultation period over the introduction of the WHO 2013 criteria for the diagnosis of gestational diabetes mellitus (GDM). Having spoken on the subject at several regional meetings, there is increasing, although not unanimous, support for the new criteria. What is absolutely agreed is that it is untenable to have two sets of criteria running in parallel – with a diagnosis depending on which hospital or obstetrician is managing the case. For the pathologists, it is impossible to report against two different sets of criteria. A small increase in the number of women diagnosed with GDM is likely; however, the therapeutic intervention for most of that increase should be diet and exercise. Anxiety from physicians and dieticians that they will be ‘overloaded’ should not transpire as I would hope that all obstetricians and midwives are capable of managing mild GDM with minimal, if any, assistance from other craft groups.

Professionalism

The Royal Australasian College of Surgeons (RACS) has been quoted in the media as being concerned with the amount of reported out-of-pocket costs being incurred by patients in the healthcare sector. RACS further went on to say that manifestly excessive fees that bear little if any relationship to use of skills, time or resources, are exploitative and unethical. As such, these Fellows are in breach of the RACS Code of Conduct and could face disciplinary action within the College.

'...there is no excuse for a failure of informed financial consent – which must be the cornerstone of ethical behaviour with respect to professional fees.'

This is not an issue that RANZCOG currently has as a priority. However, there is no excuse for a failure of informed financial consent – which must be the cornerstone of ethical behaviour with respect to professional fees. There may be a very small number of Fellows whose professional conduct risks bringing reputational damage to the Fellowship as a whole. It is my own view that the College will need to follow RACS in so far as refining its processes for managing such issues; the alternative of referring all such cases to the relevant Medical Board or Ombudsman, risks greater reputational damage to the College. Additionally, there would seem to be an increasing number of vexatious complaints against Fellows and possibly Trainees. If managed internally by the College, the fallout from vexatious complaints might be relatively contained in comparison to a Medical Board investigation.

New Board, Council and Committees

November 2014 sees the first meeting of the Ninth RANZCOG Council. Congratulations to those elected to Board and Council. Membership of the key College committees is near-finalised. All Fellows should be grateful for the extensive *pro bono* contribution made by so many Fellows, Diplomates and Trainees – from which all members of the College derive benefit. To those that believe they are clinicians and not suited to College roles, I point to numerous Councillors, committee members and College examiners who are unequivocally clinicians above all, but make an outstanding contribution to women's health beyond their day-to-day clinical roles.

Finally, having completed two years in this role, it is timely to thank all College staff, Board members, and Councillors who have supported me and the College so well during the Eighth Council. Personally, I am also incredibly indebted to very understanding university and hospital colleagues – alongside a very tolerant family. Increasingly, it is the Trainees and medical students that are teaching me – but perhaps that is the way it should be.



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From the College

Dr Ian Page
FRANZCOG
Chair New Zealand
Committee of RANZCOG

New Zealand members were delighted to learn that the RANZCOG Council recently elected two highly respected New Zealand Fellows to the 2014–16 RANZCOG Board.

Jane Cumming
Executive Officer, New
Zealand Office

Dr John Tait was elected as the New Zealand Vice President. He succeeds Dr Sarah Tout, who served in this role 2012–14. Dr Tout was a very effective representative for New Zealand in her

time as Vice President, so it came as no surprise to see Sarah re-elected as a Board member in the 2014 election.

John and Sarah are both warmly supported by New Zealand Fellows, members, trainees and staff and will continue to bring an important New Zealand perspective to Board discussions. They will also work to ensure that the needs of New Zealand members are effectively represented at the highest levels of College deliberations.

A highly experienced senior obstetrician and gynaecologist, John is executive clinical leader of the Surgical, Women's and

Children's Department of Capital and Coast District Health Board (Wellington) and one of our most involved Fellows. He is always willing to offer his expertise and is an excellent representative for RANZCOG on every level.

Along with taking on the role as New Zealand Vice President, John is involved with many other College groups, including:

- member, New Zealand Committee (Chair, 2009–13);
- member, SIMG assessment panel;
- Central ITP co-ordinator on NZTAC;
- Deputy Chair, Asia Pacific and Global Women's Health Committee (APGWHC);
- Chair, Subspecialties Committee;
- Deputy Chair, New Zealand Affairs Advisory Committee;
- Chair, Professionalism & Ethics Advisory Committee;
- member, RANZCOG Foundation Management Committee (RFMC); and
- Deputy Chair, Standards and Complaints Committee.

Beyond the College, John is the New Zealand Committee representative on the Council of Medical Colleges; New Zealand

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Committee representative on AOFOG; and Deputy Chair, National Maternity Monitoring Group.

From a College-wide perspective, John's priorities include working with the Board to develop mechanisms to allow for improved surgical training opportunities, increasing the College's profile as the primary source of information for women's health and ensuring that the College maintains a central role in discussions about recertification requirements.

At a New Zealand level, he will continue to work with others to further develop the supportive and collegial Practice Visits Program. This constructive program is highly regarded by the Medical Council New Zealand and other specialist colleges. It enjoys special status as a Protected Quality Assurance Activity (PQAA) under the Health Practitioners' Competence Assurance Act. He is also committed to the important work being done to re-establish the Maori Women's Health Committee (MWHC) and



Dr John Tait has been elected to the College Board as the representative for New Zealand.

will ensure clear communication between that group, its Australian counterpart (Aboriginal and Torres Strait Islanders' Women's Health Committee) and the Board.

John will continue to work on the major issues identified in the pre-election briefing paper provided by the New Zealand Committee to all political parties contesting the recent general election. In this paper, the New Zealand Committee emphasised the importance of government leading a national strategy to reduce the rates of unplanned pregnancies to young women and those living in deprived areas and to further reduce potentially avoidable stillbirths. In New Zealand, access to timely contraceptive services is not equitable and there are particular problems in deprived areas, especially in South Auckland.

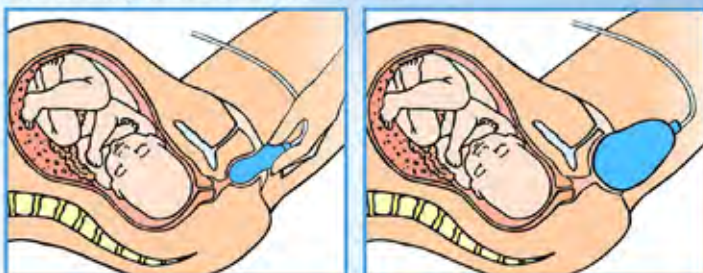
John will also continue to focus on complex workforce issues, including training, career pathways, geographical distribution of the workforce and succession planning. He will continue to vigorously protect vulnerable tertiary services such as maternal-fetal medicine and gynae-oncology.

The New Zealand Branch of RANZCOG is proud to have two such high-calibre representatives on the Board and we congratulate them and wish them every success. We know that they will add a special New Zealand perspective to discussions, which will be helpful to the overall development of the College.



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Editorial: Giving science a nudge



A/Prof Stephen Robson
FRANZCOG

'Science moves fastest when there's plenty of debate and controversy.'
– Lee Smolin¹

If it seems odd that this issue of *O&G Magazine* should look to a Harvard theoretical physicist such as Lee Smolin for its opening quote, then let me put your mind at rest. Prof Smolin is the originator of the 'fecund universes' theory – he proposes that each universe enjoys properties such

'reproduction' and 'mutation', and that processes analogous to population biology occur at the grandest scales across the cosmos. For anybody who has more than a passing interest in physics (and that rarest of things for busy doctors, spare time), Smolin's book *The Life of the Cosmos*¹ is an excellent read.

Smolin's ideas were attacked at the time, but as happens with all good science, he made predictions that were ultimately found to be true. This is the essence of scientific advancement – the development of theories that can be tested. So it is important that orthodoxies are held up to scrutiny, debated and ultimately the best ideas come to be accepted. Controversy and debate are healthy for the advancement of knowledge and knowledge underpins the work we do.

'Those who have been in practice for more than a couple of decades will recognise just how much our practice and ideas have changed within our professional lifetimes. At times, the pace seems staggering.'

This issue of *O&G Magazine* is devoted to controversy. Those who have been in practice for more than a couple of decades will recognise just how much our practice and ideas have changed within our professional lifetimes. At times, the pace seems staggering. When I was a medical student, in the early 1980s, I was taught that a 'nice snug anterior repair' was the solution for stress incontinence. By the time I became a registrar in the early 1990s, the open Burch operation was the gold standard. Today, the mid-urethral sling has become the most-studied procedure in all of medicine. In that same way, an endometrial ablation with a modified resectoscope was a major and time-consuming undertaking, at times fraught with peril. After an evolution through microwave and balloon procedures, for many women the

procedure can now take as little as a couple of minutes with new-generation techniques.

Across the breadth of our specialty, 'controversial' ideas have led to advances in care that benefit women and their families. Many of these changes were controversial at the time. Do you remember the frenetic debate that heralded the development of IVF, something that seems completely mundane now? The use of testicular sperm from azoospermic men, acquired surgically, for injection into eggs? Mesh for vaginal prolapse, now evolved into abdominal procedures to treat otherwise intractable vault prolapse? Laser treatment in monozygotic twin pregnancies to deal with twin-twin transfusion? The abandonment of pelvimetry? Uterine transplantation? Use of cell-free fetal DNA for early pregnancy screening?

What issues will we find controversial in the future? Personally, I think the next big areas of controversy are going to be pre-pregnancy screening of couples for inherited genetic traits and the use of ovarian tissue cryopreservation for women who are not yet ready to begin their families. My predictions have been wildly inaccurate in the past (footy tipping is not my forte), but both of these issues are technically easy now, but have the potential to ignite a firestorm of debate and controversy. Both might have profound effects on the next generation. Watch this space!

In this issue of *O&G Magazine* we publish the views of a number of erudite experts, guiding us through areas of controversy, and we have ventured to ask an economist to contribute – a first for us. We would like to acknowledge the enormous contribution of our authors. As always, the team here at *O&G Magazine* actively seeks feedback and debate. And, dare I say it, controversy...

Enjoy reading this issue over your summer break. Merry Christmas.

Reference

1 Smolin, Lee. 1997. *The Life of the Cosmos*. OUP. Oxford.

Controversies in training

Dr Rupert Sherwood
Immediate Past President
RANZCOG
Chair Education Strategy
Committee

Can RANZCOG still produce competent surgeons?

Earlier this year, I read a transcript of a keynote address from the USA titled: 'Why Johnny can't operate'.¹ This transcript outlines the challenges faced by surgical trainees in the USA, most of which apply to our own specialty. In this opinion piece I want to consider the current issues around surgical training in obstetrics and gynaecology.

Do we have a problem?

RANZCOG has recently (2013) been re-accredited by the Australian Medical Council (AMC) as the training program for specialist obstetrician and gynaecologists. As part of this process, the College has had to clearly define the attributes of a newly graduated Fellow.² The RANZCOG graduate can then register with AHPRA, obtain a Medicare provider number and set up in solo private practice, booking operative procedures and carrying out those procedures unassisted and unsupervised. The prospective patient has no method available to gauge the experience and expertise of the surgeon and relies on the College's assessment of competency combined with the institutional credentialing process.

Alternatively, those graduates who choose instead to commence specialist practice within the public system, either as a staff specialist or visiting medical officer, are afforded a certain degree of oversight and assistance, either planned or obtainable at short notice. However, skills attrition owing to low caseloads mandated by tight public hospital budgets remain a real risk for the new graduate.

Published surveys³ indicate a majority of these new graduates do not feel confident in their ability to undertake independent surgical practice. So, are we failing to train competent surgeons and, if this is so, why?

If we examine a generational time frame, say 30 years, and look at changes in our specialty's surgical training, we find a multifactorial causation for a significant problem that has critical implications for the continued delivery of safe care to our patients.

Key points

- Do we have a problem?
- Can we blame the trainees?
- Is obstetric and gynaecological surgery becoming more difficult?
- Is it a (Trainee) selection problem? How do we include surgical 'trainability' in the selection criteria?
- Is sub-specialisation preventing generalist training in surgery?
- Why train obstetricians (and other 'non-surgical' specialists) to operate?
- Training in private settings is, at best, a partial solution.
- Simulation has a role in training surgeons.
- How are other surgical disciplines responding to this issue?
- Does 'competent' mean 'independent'?
- Is operating enough? Why the current public health system is preventing training in holistic surgical care.

Over the remainder of this opinion piece I will examine some of those factors and offer for debate some possible solutions, keeping in mind the unalterable factors such as budgetary limits, gender balance in our specialty and the limitations to the current large *pro bono* contribution of Fellows to training new specialists.

The evolution of obstetric and gynaecological surgery

A combination of factors is contributing to the challenges of teaching surgery. These include reductions in surgical volume, restricted working hours, medicalisation of gynaecology, obesity in epidemic proportions and additional co-morbidities affecting an ageing gynaecological population. Increasing use of minimally invasive techniques leads to less open surgery, with the remaining (open) cases being complex and less suited to basic surgical training. Robotics means that the teachers are again learners, further reducing training opportunities. Intelligent integration of teaching excellence into the current operative lists is the only option, using published methods⁴ that maximise the available teaching in every surgical encounter.

You're in, you're not – selecting for a surgical specialty

Selection for vocational training is a complex and contentious issue, the only certainty of which is that with an increasing numbers of highly motivated quality candidates the process will become more difficult to get right. Objective measures of future surgical aptitude ('trainability') have some limited role in candidate ranking, but do not equate to working alongside the junior doctor in a setting that allows the qualities of a potential specialist to be assessed. Referee reports, CV and interview all have demonstrated failings for identifying those who, even with the best teachers, will retain a 'two left thumbs' rating for surgical skill. Obstetrics and gynaecology has the fallback option of the non-surgical career path, but we should not use this default to avoid continued efforts to select Trainees who can also be successfully taught surgery.

Can we blame the Trainees?

'Rosy retrospection' is the term for the cognitive bias behind the old adage 'things were better/tougher/meaner in my day' frequently quoted by successive generations over time. However, the Gen Y factor is likely to have a very limited role in the challenges facing surgical training today. It is unlikely that we will move far outside the current restrictions on overtime. The gender imbalance in the Trainee workforce (80 per cent female) makes provision for parental leave a constant with which we will have to deal when addressing surgical training. We need to set aside generational criticism and move forward when seeking solutions to training future surgeons.

It's all the fault of sub-specialisation, right?

Countering the argument mounted by Colyer in the recent MJA Insight⁵ that subspecialisation was killing generalist training and practice, Leung and colleagues⁶ have described how the subspecialties (specifically gynaecological oncology) can be actively engaged to enhance both the operative skills and general understanding of the broader surgical journey of specialist

FRANZCOG Trainees. In most tertiary centres, Fellows – subspecialty Trainees and overseas graduates on training visas – undertake surgical cases suitable for ‘generalist’ training, such as simple hysterectomy, uncomplicated pelvic floor repairs and primary mid-urethral slings. This reduces the caseload for core and advanced Trainees. Again, innovative and collaborative ways to acknowledge and overcome this seeming impasse are required and will only be achieved with strong leadership from senior clinicians who value and support equitable training opportunities across all groups.

The sensitive issue is the preferential allocation of training opportunities to overseas specialists on training visas, when local Trainees lack adequate surgical exposure. Externally funded overseas Trainees attached to subspecialty units provide assistance and after-hours cover, often to the detriment of local Trainees.

Do obstetricians need to be trained to operate?

Every time the surgical training debate is aired, the call is made to separate obstetrics and gynaecology at an early stage of the program, freeing up the gynaecological surgery training opportunities for the latter. The revised training program (with the inclusion of ‘special interest’ Advanced Training Modules [ATMs]) has recognised that the FRANZCOG qualification can no longer signify ‘is able to do everything’. It has also re-enforced the fact that obstetrics remains a surgical discipline and certain generic skills must be attained during training to ensure safe practice as a consultant. The increasing complexity of caesarean section surgery alone (obesity, abnormal placentation, other co-morbidities in an older population) dictates that division of the specialty into ‘surgical’ and ‘non-surgical’ is neither practical nor safe. The exceptions may include special interest groups such as sexual health physicians, office gynaecologists and the imaging subspecialty (COGU).

Training in private settings

RANZCOG has used the private sector for training since the Federal Department of Health initiative in 2006 (Extended Specialist Training Program) funded positions in the private sector. This continues, with some excellent opportunities provided by experienced training supervisors working with senior and mid-level Trainees within the private sector. With limited funding and competition among all the specialist colleges for the available support, this training pathway will remain a complementary rather than core part of RANZCOG surgical training.

Mentoring and group practice

Many FRANZCOG graduates will have limitations with respect to surgical expertise and scope of practice. The rewards of private practice will continue to encourage new graduates into either full-time private business or a combination of private and public work. It is timely to address the issue of mentorship and the benefits of group practice. RANZCOG has a statement on mentoring under development. The surgical personality has long encouraged a ‘coping, or being seen to be coping’ mentality, not always to the advantage of our patients. Does competent mean independent?

The answer is, definitely, no. We need to encourage recent graduates to seek advice and assistance in their formative years of practice. This is particularly important when the initial years of specialist practice are undertaken part-time and there is a very real risk of rapid skills attrition.

Who is training the teachers?

Those who have taken a Trainee through his or her first (or even tenth) major surgical procedure know the anxiety that accompanies handing over control of a complex fine motor exercise to a relative novice. Loss of the correct surgical plane, poor clamp placement, poor knots and other variations from the teacher’s well-established procedural steps can cause supervisor and Trainee distress and loss of confidence for both. Some good surgical teachers are born, but others have to learn these skills. To counter this, a structured approach to each operating room encounter designed to maximise the benefit of teacher-Trainee interaction is crucial. Each Trainee will have differing needs for the same operation, the junior wanting to confidently enter the anterior peritoneal space (without cystotomy) at vaginal hysterectomy, and the senior Trainee keen to master the debulking myomectomy of the large uterus with inaccessible pedicles. This structured approach should become an integral part of every major surgical procedure undertaken by Trainees. Leung et al⁴ have published a validated template for the surgical encounter that maximises the learning opportunity of each operation. Surgeons responsible for teaching need to actively seek out those ‘trained teachers’ who can guide them towards becoming that elusive boss with whom everyone on the training program wants to work.

There’s more to surgery than operating

Good surgical results start in the consulting room, not the operating theatre. Knowing when not to operate is far harder than knowing when to operate, and the teaching of those skills requires a similar investment of time and resources to that required in the theatre. Managing a bad outcome requires far more skill than managing a success. The RANZCOG curriculum covers communication, peri-operative assessment and the difficult patient. However, the Trainee’s first contact with the patient may be the holding bay or anaesthetic room of the theatre. Many factors outside the control of the surgeon and Trainee mitigate against continuity of care for the surgical case, with some hospitals outsourcing outpatient services, and enforcing rosters so restrictive in hours it is pure chance if a Trainee sees a patient through from admission to discharge. Specialisation should not preclude holistic care of patient and family.

Don’t bring me problems, bring me solutions

Problems in obstetric and gynaecology surgical training are neither new nor immediately solvable. Strategies to address the issue include:

- Reducing the intake of accredited trainees from 2016 onwards.
- Expanding the current ‘teach the teachers’ programs to focus on surgical training.
- Prioritising the College e-Logbook project to allow real-time access to Trainee procedure numbers.

- Expanding the role of simulation in our training.
- Supporting mentorship and group practice for new graduates.
- Restricting overseas specialists using training positions that could be allocated to local Trainees.
- Including core Trainees in the subspecialty operations, using parts of complex procedures to teach general skills (for example, the mid-urethral sling that is part of a complex pelvic floor repair, the hysterectomy that is part of a complex gynaecological oncology case and so on).
- Working in active collaboration with the other surgical colleges to find solutions to a shared problem.

In conclusion, I believe we should actively engage all stakeholders across the surgical disciplines to seek immediate and sustainable solutions to the problems besetting surgical training. This is the role of the specialist medical colleges – to act as leaders and facilitators in curricula writing, standard setting and assessment to ensure that the graduates meet community needs and expectations in holistic surgical care.

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A guide to writing guidelines



Prof Ian Hammond
Chair, Steering Committee for
the Renewal Implementation
Project
**National Cervical Screening
Program**

So, you want to write a clinical guideline: how to avoid falling off the cliff.

If someone asks you to write a clinical guideline or be involved in developing a new health policy, you could be forgiven for saying: no! This is tough, time consuming and has driven many good people to a state of frustration and disbelief, verging on despair.

Busy clinicians require support for their patient-related decision-making and

this should be provided by evidence-based clinical guidelines. Who better to develop such materials than clinicians with expert understanding of the health problem under consideration and the specific areas requiring guidance. Sadly, clinicians are time poor, often lack experience and confidence in such activities and would be pleased if someone else would do the job, though the very same clinicians are the first to complain about a new guideline or policy, especially if it doesn't fit with their 'clinical experience' or personal view of the matter.

Three tales of guideline/policy development

I have had the opportunity to be involved in the development of both guidelines and policy at a national level. My initial foray was as Chair of the Guidelines Review Group responsible for the development of National Health and Medical Research Council (NHMRC) endorsed 'Screening to prevent cervical cancer: guidelines for the management of asymptomatic women with screen detected abnormalities', which finally saw the light of day in 2005 after a protracted, difficult and damaging process. The previous NHMRC guidelines were out of date and needed review. We followed the NHMRC process¹, and this was time consuming, expensive and difficult to keep to desired timelines. An anticipated two-year involvement became five years owing to the rigour of the NHMRC process and the unexpected vociferous opposition and personal attacks from some quarters, despite the quality of the evidence supporting the recommendations.

Much of the difficulty resulted from a lack of initial consultation and discussion with those affected (the stakeholders) and not providing them with a forum to participate, contribute and voice possible concerns at the outset. Public consultation over draft documents is a mandatory part of the NHMRC process. Early consultation is not. In my opinion, early and ongoing involvement of potentially affected stakeholders (partners in the process) is critical to acceptance of new guidelines/policy/strategies. Failure of some representative committee members to voice their concerns until very late in the process was also unhelpful. Speak out and speak early!

The main controversy resulted from reluctance to accept the safety of one recommendation, namely a 12-month delay in colposcopy for possible or definite low-grade squamous intraepithelial lesions.

We were blindsided by vocal and public opposition (not supported by evidence of harm) that gained substantial media publicity producing confusion and doubt among health professionals, consumers and the NHMRC committee charged with reviewing and endorsing the guidelines. This resulted in a frustrating 12-month delay and significant further work and expense, in order to finalise and gain NHMRC approval of these necessary national guidelines. Subsequent monitoring of these guidelines has demonstrated their safety.²

My second effort was as Deputy Chair (Chair: Alison Brand) of a Working Party developing 'Clinical practice guidelines for the treatment and management of endometrial cancer', under the auspices of, and endorsed by, the Cancer Council Australia (CCA), to be published in a Wiki format for web-based access and timely revision as needed.³ The expert multidisciplinary membership was responsible for defining the scope of the guidelines, assessment and defining the level of the evidence (systematically collected by the CCA Secretariat) and writing the relevant chapters of the document. Early consultation with stakeholders was not deemed necessary owing to the nature of the task. Nationally accepted guidelines for endometrial cancer management were not available, though most treating institutions had local guidelines, and national consensus though desirable was lacking. Public consultation of the draft guidelines (with health professionals, specialist colleges and societies and consumers) was constructive with little dissent and general acceptance. Those potentially affected were few in comparison with the 'screening to prevent cervical cancer guidelines' and this was predominantly documentation of current evidence-based practice rather than a substantial change to current and accepted practice requiring attention to the principles of change management processes.

My most recent involvement has been Chair of the Renewal Steering Committee (RSC), National Cervical Screening Program (NCSP), Federal Department of Health Australia, charged with steering the process of the renewal of that program (and developing new government policy) in the light of new evidence about cervical cancer prevention and screening, new technologies and a changed health environment, including human papillomavirus (HPV) vaccination. This process, under the auspices of the Department of Health, reviewed the evidence around cervical cancer prevention and screening, with subsequent economic and health outcome modelling. The systematic evidence review was carried out by a nationally recognised group from the University of Sydney, answering questions that were formulated by the RSC and a Partner Reference Group, composed of interested health professionals, industry and consumer groups. This early consultation and involvement of the Partners and their ongoing involvement with further critical consultations and e-newsletters was a major factor in the success of the process. An informed, dynamic and responsive Secretariat was essential to maintaining timelines. Also important was the involvement of the expert government Medical Services Advisory Committee and its processes in the review of the evidence

and economic modelling documents, leading to authoritative and independent evidence-based recommendations regarding the renewed cervical screening program.⁴

Guidelines versus policy

Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances. They are usually not considered to be compulsory or mandatory, but are 'guidance' as to current evidence-based best practice and should have a positive impact on healthcare. Clinicians who choose not to follow local or nationally accepted clinical guidelines, should ensure adequate documentation of their reasons and discussion with the patient, for in the event of a poor clinical outcome or subsequent 'issues' there is always the potential for medico-legal action.

Policies are the principles, rules and procedures formulated or adopted by an organisation (such as a hospital, health department or business) to reach its long-term goals (such as improved healthcare, patient and staff safety and so forth) and are, typically, published in a widely accessible format. They are usually considered to be compulsory and, in terms of national health policy, form the basis for the ongoing funding of specific health programs. Policies may change based on new evidence, as typified by the recent Renewal of the NCSP (see above⁴), where a change from two-yearly Pap testing from age 18–69 to five-yearly HPV partial genotype testing every five years from age 25–74, has been recommended and recently supported by the Australian Health Ministers Advisory Council.

Getting it right

I will focus my comments on guideline development, as this is the most common involvement for clinicians. The NHMRC provides leadership and exhaustive (and exhausting!) documentation¹ for those wishing to develop clinical guidelines to be approved by the NHMRC or who seek guidance regarding an acceptable and robust development process. Clinical practice guidelines should be based on the systematic identification and synthesis of the best available scientific evidence and make clear recommendations for health professionals practising in an Australian healthcare setting. The NHMRC requirements for developing clinical practice guidelines are designed to ensure this standard is upheld.⁵ These requirements are summarised below.

Clinical guidelines should:

- provide guidance on a clearly defined clinical problem based on an identified need;
- be developed by a multidisciplinary group that includes relevant experts, end users and consumers affected by the clinical practice guideline;
- include a transparent process for declaration and management of potential conflicts of interest by each member of the guideline development group;
- be based on the systematic identification and synthesis of the best available scientific evidence;
- make clear and actionable recommendations in plain English for health professionals practising in an Australian healthcare setting;
- be easy to navigate for end users;
- undergo a process of public consultation and independent external clinical expert review; and
- incorporate a plan for dissemination including issues for consideration in implementation.

When considering developing or reviewing clinical guidelines, it is important to ask the following questions:

1. Why are these guidelines needed and for whom are they intended?
 - a. Are they new guidelines for a new technology or intervention (drug or technique)?
 - b. Are they a 'revision' of outdated guidelines?
 - c. Are the existing guidelines really out of date, or have they come to their previously determined 'use by date' and need review to ensure relevance?
 - d. Are guidelines needed to assist the procedural process resulting from a new overarching policy decision (like Renewal of the NCSP)?
 - e. Is there a general understanding and agreement (by those affected) that new guidelines (or policy) are in fact needed?
 - f. Is there known new information that puts the current guidelines 'at risk' of being dangerous or irrelevant?
 - g. Is this an urgent matter and, if so, is the reason for urgency understood?
 - h. Is it a multi-disciplinary issue and, if not, could a specialist group be sufficient to develop the guidelines (such as colposcopy or similar procedure or topic)?
2. Who should develop/revise these guidelines?
 - a. Is a small or large group of people needed?
 - b. Which disciplines need to be represented?
 - c. Is a representative of the Aboriginal and Torres Strait Islander community included?
 - d. Would the presence of a 'consumer' aid the process – usually essential?
 - e. Should the members be 'individuals' or 'representatives' of organisations (sometimes individuals with recognised expertise may be more efficient and more interested in getting the job done)?
 - f. Is previous experience of guideline development necessary or desirable?
 - g. Who will gather the evidence and perform a systematic review?
 - h. Who is responsible for choosing the people to be involved?
 - i. Who will write the document?
 - j. Is there sufficient expert secretarial support for this process?
 - k. Governance: who will Chair the group, how will the Chair be chosen and who will it report to?
 - l. Who will be funding this process and the implementation phase?
 - m. Is the funding realistic?
3. What should be included in the scope of the guidelines: terms of reference?
 - a. What are the overarching policy and principles?
 - b. Is there agreement as to the scope of the topic?
 - c. If not, who is responsible for defining the scope?
 - d. Is the scope 'realistic' and achievable in the timeframe (see below)?
4. When should this task be completed?
 - a. What are the timelines for the various parts of the guideline development and its implementation?
 - b. Is this realistic?

- c. Are the members of the guideline group able to commit the time needed and participate actively in a timely fashion?
 - d. Is there a built-in buffer for unexpected delays?
 - e. Enthusiasm/output among committee members may wane with time, has this been accounted for?
 - f. If markedly delayed, the guidelines could be out of date by the time of publication – how will this be resolved?
5. How should this process be carried out?
- a. Does this process require an expert multidisciplinary group?
 - b. Have potential conflicts of interest in the group been identified and addressed?
 - c. Is the NHMRC guideline development process⁵ to be followed either completely or in part, or is there some other recognised authority (professional body, specialist college, university) to guide this process?
 - d. So that the guidelines cannot be dismissed as without authority or credibility, ill informed, biased or irrelevant, has the process (and its authority) been clearly defined at the outset?
 - e. Has an implementation plan been defined early in the process?
 - f. To help prevent much dissension and heartache down the track, has consultation with all stakeholders been considered at the beginning of the process?
 - g. If necessary, has it been determined how to capture dissenting evidence, but still move forward?
 - h. Has an online interactive 'tool kit' to complement the guidelines and facilitate their ease of use been considered and developed?

Finally, guideline (and policy) development offers clinicians the opportunity to get involved in large-scale improvements to healthcare and is a worthwhile mechanism to make a contribution to the community we serve. I hope that by considering my suggested approach of Why, Who, What, When and How, that your involvement will be productive and rewarding.

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The 'dismal science' of birth

Louise Rawlings PhD
Economist

Turning an economist's eye to having a baby.

When it comes to having a baby, everyone has an opinion. Economists certainly love telling people what they think and pregnant economists might be the worst of all. American economist Emily Oster did her best to set the economic cat among the medical pigeons in 2013 with the publication of: *Expecting better, why the conventional pregnancy wisdom is wrong – and what you really need to know*.

Confused by the advice she received about healthy living during her pregnancy, Oster did what economists often do and set about summarising existing studies about a wide range of pregnancy issues to give the 'bottom line', as an economist might see it, from the available data. Oster covered issues of interest to many pregnant women such as intake of caffeine, alcohol, tobacco, the risk of infection with listeria and toxoplasmosis, as well as prenatal screening and testing, drug safety, bed rest, induction of labour and pain relief for birth. Her book also usefully raised issues central to economics around 'trade-offs' and the 'continuum of risk'. Every pregnant woman thinks differently – each might make different decisions, and each will have different tolerances to caffeine, alcohol and so on.

Oster's book attracted considerable criticism. An economist writing about pregnancy? People often presume economics deals exclusively with money and investments. In reality, other than having an understanding of the advantages of investment in indexed funds, most economists know very little about the share market. Economics is really about the choices people make, given that we cannot have everything we want. It is about trade-offs and knowing what you are giving up in order to get something else. Everything has a cost and that can also mean foregone opportunities. Economists usually believe 'opportunity cost' guides rational decision-making in every sphere of life and they are trained to get the data and then use those data in conjunction with risks, benefits and decision-theory to make choices. Economists are data driven. So, in examining how economists think about data, causation, correlation, what makes a good study, trade-offs and the risk continuum, Oster's book made a useful contribution to both economics and medicine.

Choices

Not everyone will make the same choices faced with the same data. But, as Oster acknowledges, it can be difficult even to obtain data about issues in pregnancy. This is not only because it is difficult to tease out cause and effect, but also because there are almost insurmountable legal and ethical issues that make further research into some areas of pregnancy incredibly challenging. There are some areas where it is unlikely clinical trials will ever be run.

The economy, like the body, is a complex system in which it is very difficult to measure cause and effect. There are great amounts of data and many statistical techniques are used to try to isolate the impact of one variable on another. In economics, there are not normally real experimental data with a 'control' group. There are some experimental data in microeconomics (the study of individual units and business decisions), but there is no control group in macroeconomics (the 'business cycle'). There are natural experiments

– things that happen in the world are assumed to be exogenous – and we can compare before and after. There are also empirical studies that use statistical evidence to try to tease out the individual effects of different variables by holding other things constant. However, in the wake of the global financial crisis (GFC), there has been robust debate in economic circles around the statistical techniques employed.

Economists are examining these data issues and are making suggestions for the future. Perhaps there are empirical lessons different disciplines can learn from each other. When we are dealing with complex systems, such as the body and the economy, it may be time to reweight the hierarchy of evidence and consider other forms of evidence.

Data, causation and correlation

The hierarchy of medical evidence is the major construct of evidence-based medicine (EBM). Randomised controlled trials (RCTs) and meta-analyses (MAs) sit at the pinnacle and are often seen as trumping other forms of evidence. Observational studies, case reports, personal experience and physiological considerations usually sit well below. Higher levels of evidence trump lower levels.

With most pregnancy research there is a very clear problem with causality. Caffeine provides a good example of this and Oster includes an interesting discussion of caffeine consumption in pregnancy in her book. The perceived concern with having too much caffeine in pregnancy is it might cause miscarriage in early pregnancy. Oster found all of the studies suggest that up to 200mg of caffeine per day is safe and that there is not an increased risk of miscarriage up to that level. When she examined studies of women who reported much higher levels of caffeine consumption, she found the evidence suggested there was an increased risk of miscarriage. The evidence for the 'middle range' of caffeine consumption was mixed.

Oster points out in pregnancy it is difficult to establish causality and she suggests women who drink a lot of coffee are probably different from those who do not. The data suggest women who drink coffee tend to be older and that cannot be controlled for. She also points out there is also a problem with nausea. Nausea in early pregnancy tends to be a good sign: women who are nauseous are less likely to miscarry. However, women who are nauseous are also more likely to avoid coffee. So, women who drink a lot of coffee are also women who, on average, are less nauseous. When it is then considered that they miscarry at higher rates, it may well just be that not being nauseous is a sign of miscarriage, not that the coffee caused the miscarriage. Trying to understand the impact of caffeine consumption on pregnancy can lead to 'spurious correlations' being drawn. It might be that the thing you cannot measure or have not measured is actually the underlying causal variable.

In her book, Oster usefully considers the types of evidence that are used for pregnancy research. Observational studies could be used:

a group of people could be asked retrospective questions about their behaviour during pregnancy. This, however, is not ideal. For example, if they have learned certain behaviours during pregnancy were not socially acceptable they might lie, or unintentionally 'misremember' their past behaviour. Oster is clearly of the EBM school and places randomised data on a pedestal in order to try to tease out causation. There might be a number of areas of pregnancy where there are randomised data. However, such studies are also not without their downsides. They are expensive. They are run typically in one population, not in all populations. Is a finding significant in terms of size? The studies may also be outdated and could usefully be revisited. For example, there might be different technology available now. However, it might not be possible to run another trial because it might be more difficult to be granted ethical approval now than when the study was initially undertaken. It may not be deemed acceptable practice to ask a group of pregnant women to drink a large amount of coffee and another group not to, to obtain new data.

Researchers are often quite passionate advocates for a certain pet hypothesis and not as interested in refuting it. A common assumption among researchers is that if you did not get the answer you expected you did the experiment incorrectly. It becomes very hard for new data to convince proponents otherwise. In economics, as in epidemiology, beliefs are often masked in the language of science, precisely what proponents of EBM are seeking to overcome. Sometimes that debate is not about data, but about dogma.

Let me provide an example from economics. If you are a Keynesian and believe government spending creates prosperity in the face of a recession, something many economists have been advocating post-GFC, what evidence would dissuade you from that belief? Certainly predicting eight per cent unemployment after the US stimulus package and getting ten per cent has not really dissuaded any Keynesian economists. The response has been broadly 'the GFC was worse than we thought!', or 'we didn't spend enough'. Often the more certain and confident the researcher, the more dismissive they are of their ideological opponents, and the bigger their platform. There is an incentive to reconfirm what the researcher already believes. As well, the more exotic and dramatic the result, the more likely the research will be featured in the media. There is a bias towards incredible claims and journals can be just as guilty of this bias and generally only publish positive results. Surely the evidence base should also include negative results?

In epidemiological terms, examining the relationship between coffee and miscarriage is very similar to economic analysis of the relationship between a stimulus package and employment. Papers will be accompanied by a table or a chart that supposedly shows that the relationship between the two variables is of a certain magnitude and not owing to chance. However, readers do not see all the different regressions that were done before the chart was finished. The chart is presented as objective science. If you have not been shown all the steps, it is not clear whether the findings are robust. There is a focus on finding something in the data set. However, there might not be anything in the data set, the set might be too small or the assumptions may not be credible. As one wit once quipped, 'statistics are like swimsuits – what they reveal is interesting, but what they conceal is vital!'

There are also well-documented issues associated with MAs. MAs are essentially observational studies in which the studies themselves are the subjects. The major difference between conclusions drawn

in different MAs is the choice made of which studies to include and which ones to exclude. Yet authors maintain their criteria for exclusion are valid even though they are sometimes quite different and result in quite different conclusions. The justifications for the inclusion or exclusion of studies from the evidence often rest on competing claims of methodological authority. In many ways, these are no different to the traditional claims of medical authority that proponents of EBM have criticised. Again, the various statistical techniques used to analyse the data also require consideration. Arguments between statisticians on statistical methods are often impenetrable to all but the ultra-specialist. Doctors reading and relying on MAs are usually not aware of the thick methodological-statistical layer that underpins them.

Novel methods

It may be that a revolution is occurring in the way economics is done. Arguments have been made for the use of more sophisticated statistical techniques to analyse complex systems, with the power of data and analysis ascendant over more traditional decision-making methods based on judgment and intuition. Yet there is no such thing as a completely exogenous variable in either epidemiology or economics, and drawing conclusions from such experiments takes the same kind of work it takes to draw conclusions from non-experimental or observational data. In macroeconomics that jump is taken all the time.

If you want to know whether government spending has a multiplier effect, then you have to have a 'treated group' and a 'control group' just as doctors are used to. Just because, in the past, a government spend of a billion dollars had a particular impact on the economy, the complex nature of economies means that the outcome might be very different in the next recession. In the case of macroeconomics, it is very difficult to conceive a study to make conclusions about the impact of stimulus programs. Defence spending comes to mind; comparing the end of war with the start of war. While it might seem logical to draw the conclusion that defence spending has historically stimulated the economy, the scientific nature of such conclusions are somewhat problematic. The same could be said for epidemiology.

Where to from here

Some economists have dismissed all empirical work as flawed. That is wrong – no single path will ever provide the complete solution. While randomised trials are appropriate for addressing simple questions, they are practical for only a small number of issues. Even when evidence is available from high-quality RCTs, evidence from other study types can often be very relevant.

Proponents of EBM make a conceptual error in relegating clinical experience to the lowest rung. It is judgment that determines what evidence is admissible, and how strongly to weigh different forms of evidence. Judgment is integral to, and cannot be excised from, the process of evidence synthesis. The EBM evidence hierarchy otherwise becomes a means to avoid judgment. Patients seek specialist advice because specialists have considerable experience. The hope is doctors put all the other evidence in context.

And what of Emily Oster herself? Emily's daughter, Penelope, seems to be a healthy toddler. Whatever she did in her own pregnancy, it definitely seemed to work. Let's leave her the last word. 'Is it okay to use dish soap during pregnancy? Is it okay to eat a lot of potatoes? What about using those whiteboard markers that smell so bad? At the end of the day, we may have to just admit we are accepting some baseline level of risk by just living, and, well, live with it.'

Age-old questions

Dr Lucille Wilkinson

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Health Board, New Zealand**

In the era of very advanced maternal age, what do we know and what is yet to be determined?

Before the development of donor oocyte therapy, the upper limit of reproductive age for women was determined by low conception rates once women were over the age of 40. Advanced reproductive technologies, introduced as treatments for infertility and premature ovarian failure, have now been increasingly used to assist perimenopausal and postmenopausal women to achieve pregnancy. This has led to uncharted territory when it comes to pre-pregnancy risk assessment, antenatal care and peridelivery management. Medium and long-term outcomes for these women and their offspring remain largely undetermined.

Epidemiology

It is estimated that there were around 2000 donor oocyte cycles performed in Australasia in 2010, with nearly 30 per cent of recipients being over 45 years of age. Australasian women also seek donor oocyte and embryo treatment overseas, with estimates of more than 500 babies born each year in Australasia following conception with donated oocytes from overseas.¹

The rates of donor oocyte cycles provided to woman over the age of 50 years in the USA have more than doubled between 1998 and 2010.² The popularity of this treatment is driven by the increased chance of a successful live birth; with women over 45 years of age having an over 50 per cent success rate compared to 1.8 per cent success rate using their own oocytes.³

It is likely that increased recipient age over 45 years is associated with small, but progressive, declines in favourable reproductive

technology outcomes (implantation, clinical pregnancy, live birth and miscarriage), compared to outcomes for younger recipients. Live birth rates remain high in the age cohorts over 45 years – 52.7 per cent and 48.6 per cent for women aged 45–49 and >50, respectively.⁴

Outcomes of pregnancy

The Canadian Institute for Health information has reported outcomes across maternal age groups for primigravida singleton pregnancies that indicate increasing risks with age, especially for delivery by caesarean section (see Figure 1).

While there is a progressive impact of advanced maternal age over 35 years on pregnancy outcome, there is a remarkably small volume of outcome data for women of very advanced maternal age (VAMA, defined as >45 years) in either the Australasian or international literature. The more recent information that exists pertains increasingly to outcomes from donor oocyte programs. Most series are of limited size and therefore report only frequent outcomes such as gestational diabetes, hypertensive disorders of pregnancy, preterm delivery, mode of delivery and rates of small for gestational age babies (see Tables 1–3). It is not possible to determine the risks of less-frequent maternal and neonatal outcomes, such as maternal and neonatal death, postpartum caesarean section, placenta accreta/percreta and maternal cardiac events.

The literature reports a wide range of risk of adverse maternal outcome and therefore makes it difficult to predict outcomes for pregnancy in women over the age of 45 years. It is not possible

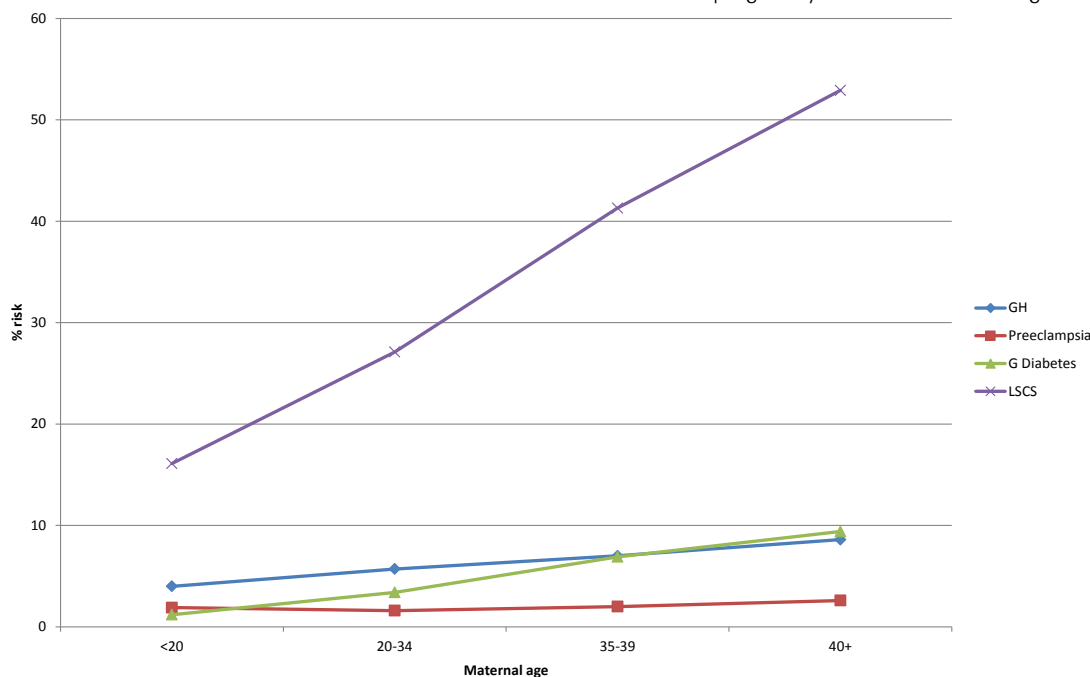


Figure 1. Pregnancy outcomes by maternal age – Canadian Institute of Health.²⁰

to determine that 'pre-screening' women for medical suitability for pregnancy reduces the risk of maternal adverse outcomes.

There are two reported episodes of maternal death in women over the age of 50 years after donor oocyte therapy. One death occurred from intracerebral haemorrhage in the setting of HELLP syndrome¹⁴ and one occurred from acute cardiac arrest.¹⁵

The largest report of outcomes for pregnancy in advanced maternal age (>40) from California described the outcomes of more than 24 000 pregnancies between 1992 and 1993. They described a pre-eclampsia rate of 5.4 per cent and a gestational diabetes rate of seven per cent in nulliparous women.¹⁶

The literature confirms the high rates of delivery by caesarean section in VAMA pregnancies. The underlying reason for this high rate may be influenced by rates of multiple pregnancies following fertility treatment, concerns regarding maternal age and post-dates delivery and neonatal concerns.

Adverse perinatal outcomes are increased in all series compared to outcomes of pregnancy in woman of lower maternal age. Rates of preterm birth are elevated and SGA is high in most studies. This represents a higher risk of neonatal unit admission, prolonged neonatal hospital stay and potential for medium- and long-term medical complications during childhood. Donor oocyte therapy is associated with high rates of multiple pregnancy (15–39 per cent), which is associated with an increased risk of maternal and perinatal adverse outcomes.¹⁹ The high rate of multiple pregnancy could be reduced substantially by adhering to recommendations to avoid transfer of more than one embryo at a time, when oocyte donors are of a younger age.²²

Although the immediate outcomes of VAMA pregnancies are reported in small numbers, there is a lack of follow-up data to answer very important questions:

- Is there a higher risk of poor recovery from pregnancy complications for these women? This is particularly relevant for hypertensive and diabetic complications, which are known to potentially predict future development of cardiovascular and metabolic disease.
- What is the risk of rare but serious complications that could be associated with advanced maternal age? These potential complications may include peripartum cardiomyopathy, pregnancy related myocardial infarction, venous

Table 1. Maternal outcomes in VAMA.

Author	Country	Year	n	IVF only	Hypertension	Preeclampsia	GDM	Age
Jacobsson ¹⁷	Sweden	1987–2001	1205	no	3.4%	2.2%	4.7%	>45
Paulsen ⁵	USA	1991–2001	40	yes		35%	20%	>50
Sauer ¹⁸	USA	1990–1994	74	yes	11%	2.7%	8.1%	>45
Sheffer ⁶	Israel	1995–1999	41	yes	30%		24%	>45
Simchen ⁷	Israel	1999–2004	123	no	28%	9.8%	21%	>45
Callaway ⁸	Australia	1992–2001	76	no	13%		8%	>45
Yogev ⁹	Israel	2000–2008	177	no	16%	11%	17%	>45
Glasser ¹⁰	Israel	2004–2008	131	yes	42%	18%	43%	>45
Carolan ¹¹	Australia	2005–2006	217	no		4.6%	9.7%	>45
Jacquemyn ¹²	Belgium	2005–2010	421	no	11%		7.6%	>45
Le Ray ¹³	France	2008–2010	380	yes		8.7%	6.1%	>43
Kort ¹⁵	USA		101	yes	23%		3%	>50

Table 2. Mode of delivery and obstetric complications in VAMA.

Lead author	Instrumental delivery	LSCS delivery	PPH
Jacobsson ¹⁷	4.7%	30%	
Paulsen ⁵	6%	78%	
Sauer ¹⁸		65%	
Sheffer-Mamouni ⁶		72%	
Simchen ⁷		75%	
Callaway ⁸	3.9%	49%	
Yogev ⁹	3.4%	79%	
Glasser ¹⁰		94%	
Carolan ¹¹		55%	9.7%
Jacquemyn ¹²	8.3%	43%	
Le Ray ¹³		45%	7.4%

- thromboembolism, and placenta accreta or percreta.
- What are the long term outcomes for children born to women of VAMA? We might expect an increase in complications already recognised as higher risk in adults who were born prematurely or SGA.

Counselling women prior to treatment

It is recommended that women have pre-pregnancy review and counselling by a clinician experienced in caring for women with potentially high-risk pregnancy.^{1,20,22} This clinician may be a physician with obstetric medicine training or an obstetrician with either maternal-fetal medicine training or with substantial experience caring for high-risk pregnancy. It is not known whether medical review of older women considering pregnancy offers any benefit with regards to predicting adverse outcome or offer any preventative role in improving pregnancy outcomes.

It would seem reasonable for all women considering pregnancy beyond the age of 45 years, or at a younger age if they have pre-existing medical issues, to have the opportunity to have pre-pregnancy advice from an independent expert medical practitioner. This review should include:

- a full personal and family medical history;
- a review of regular medications and the consequences of these

Table 3. Perinatal outcomes in VAMA.

Lead author	Preterm <37/40	Preterm <34/40	SGA	Perinatal mort.
Jacobsson ¹⁷	9.4%	3.5%	5%	1.4%
Sheffer-Mamouni ⁶	15%		7.6%	
Simchen ⁷		14%	34%	
Callaway ⁸			10%	2.6%
Yogev ⁹	22%	6%	11%	
Glasser ¹⁰	34%		29%	
Carolan ¹¹	17%		11%	1.3%
Jacquemyn ¹²	17%	9.2%		3.6%
Le Ray ¹³	19%	7.9%	28%	

for pregnancy;

- a medical examination including weight, height, cardiovascular examination and general examination;
- up-to-date recommended screening tests including cervical smear testing, breast screening and bowel and skin cancer screening for those at higher risk;
- standard blood tests including renal, liver and thyroid function, antenatal bloods and diabetes screening (either an HbA1c or a glucose tolerance test in higher risk patients);
- a chest radiograph and lung function testing for long-term smokers or those with respiratory symptoms;
- a discussion regarding the potential risks of pregnancy for themselves and for potential offspring, including the possibility of maternal hospitalisation, preterm delivery and operative delivery;
- advice to avoid fertility treatments that substantially increase the risk of multiple pregnancy; and
- advice regarding optimal prenatal and pregnancy care,

including exercise, diet, weight loss, prenatal vitamin intake, specialist obstetrician oversight and a discussion of the potential modest benefit of low dose aspirin and calcium supplementation. If a woman is contemplating donor oocyte therapy, then a delay in treatment to optimise her own health is likely to be beneficial.

This review should be additional to the counselling routinely provided by fertility treatment providers and be provided by a clinician with no financial interest in the woman proceeding with fertility treatment.

Societal and ethical considerations

Increased maternal and neonatal complications secondary to VAMA pregnancies will result in increased financial and resource cost to the public health system in both the short term and potentially the long term for babies with complications of prematurity. It is unlikely that this has been taken into account in future planning for funding and planning of antenatal and neonatal services.

VAMA is often accompanied by very advanced paternal age (VAPA). The consequences for offspring of VAPA are not well defined, but may include an increased risk of new gene mutations, fetal congenital malformations, schizophrenia and autistic spectrum disorder.²¹

Ethical issues with assisting women to achieve VAMA pregnancies are considerable.²² It is ethically warranted to decline to provide treatment to women who have underlying medical conditions that may further increase maternal or neonatal risks. Fertility treatment providers must take responsibility for ensuring an appropriate and ethically defensible decision is made. There is a lack of data regarding any potential long-term adverse medical and psychological outcomes for oocyte donors, which could be rectified by longitudinal follow up by fertility service providers.²³



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There is no evidence of social or psychological adverse effects for children with older parents, but the risk of age-related parental illness or death occurring earlier in a child's life is likely to be increased. The health of both parents should be taken into consideration when determining this potential risk.

Conclusion

Advances in reproductive technology, particularly donor oocyte and donor embryo programs, have opened a door, allowing increasing numbers of women to undertake pregnancies at VAMA. Providers of these treatments have a professional, ethical and moral obligation to ensure that prospective parents understand the potential risks of these pregnancies and have access to independently provided medical assessment and counselling. The long-term implications for children born to mothers of VAMA and the consequences for the health system remain undetermined.

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Preventing pre-eclampsia



Dr Andrew McLennan
FRANZCOG COGU

First trimester screening and preventative treatment for early-onset pre-eclampsia – new research offers interesting answers.

Pre-eclampsia is defined as hypertension (≥ 140 mmHg systolic or ≥ 90 mmHg diastolic) usually developing after 20 weeks gestation with one or more co-existent conditions such as proteinuria, other maternal organ dysfunction or placental dysfunction.¹ It affects between two and five per cent of all pregnant women and is the leading cause of maternal and fetal morbidity and mortality.^{2,3} Early onset pre-eclampsia resulting in delivery before 34 weeks gestation affects approximately one in 250 women.⁴



Dr Greg Kesby
FRANZCOG CMFM

Pre-eclampsia is a multisystem disorder of unknown aetiology, but is associated with dysfunctional placentation (poor cytotrophoblast invasion and impaired spiral arteriole

remodelling), leading to an abnormal maternal physiological response to the underlying vascular endothelial dysfunction and consequent imbalance in both local and circulating angiogenic factors. This is expressed as a second- or third-trimester syndrome of maternal hypertension associated with uteroplacental insufficiency and/or impairment of maternal end-organ function.⁵

It is an obstetric axiom that pre-eclampsia can only be cured by

Table 1. Risk factors associated with pre-eclampsia (adapted from Lowe et al).⁷

Risk factor	Unadjusted relative risk [95% CI]
Previous history of pre-eclampsia	7.2 [5.9, 8.9]
Antiphospholipid syndrome	9.7 [4.3, 21.8]
Pre-existing diabetes	3.6 [2.5, 5.0]
Multiple pregnancy	2.9 [1.3, 6.6]
Nulliparity	2.9 [1.3, 6.6]
Family history of pre-eclampsia	2.9 [1.7, 4.9]
Overweight (BMI 25–29.9)	1.7 [1.2, 2.4]
Obese (BMI ≥ 30)	2.7 [1.7, 4.4]
Maternal age ≥ 40	2.0 [1.3, 2.9]
Systolic BP > 130 mmHg < 20 weeks	2.4 [1.8, 3.2]
Diastolic BP ≥ 80 mmHg < 20 weeks	1.4 [1.0, 1.9]

delivery of the fetus and placenta. Indeed, with deference to severity, this is the preferred management strategy when the gestational age is at term or close to term. The dilemma arises where pre-eclampsia is diagnosed before 35 weeks gestation, where the maternal and fetal morbidity and mortality are seen to increase owing not only to the presence of disease at an early gestation age (which may prompt preterm caesarean delivery), but also as a consequence of the maternal and fetal risks associated with the relentless progression of the disease if pregnancy is prolonged in an attempt to improve fetal maturity.

There is another axiom in medicine: prevention is better than cure. However, effective prevention requires appropriate identification of the at-risk group, together with an intervention that will mitigate or eliminate development of the pathology.

With regard to identification of an at-risk group, over the last 30 years obstetricians have relied on obstetric, medical and family history to identify women at high risk of developing pre-eclampsia (see Table 1). Unfortunately, this screening method identifies only approximately 30 per cent of cases and has a high false-positive rate.⁶

A number of other factors are also associated with an increased risk of pre-eclampsia including maternal age (< 20 years or ≥ 35 years), chronic hypertension, pre-existing renal disease, autoimmune disease, more than ten years since the previous pregnancy, short sexual relationship prior to conception and possibly periodontal disease.^{8,9,10}

More recently, as a result of experience with multi-parameter Bayesian risk assessment algorithms used in first trimester aneuploidy screening, it has become possible to identify pregnant women at increased risk of early-onset pre-eclampsia on the basis of a combination of maternal demographic and historical features, biophysical parameters (body mass index, mean arterial blood pressure [MAP], Doppler assessment of placental vascular resistance at 12–14 weeks gestation – uterine artery pulsatility index [UA PI]), and maternal serum analytes (principally pregnancy-associated plasma protein A [PAPP-A] and placental growth factor [PlGF]). On combining these parameters in a validated risk algorithm (Fetal Medicine Foundation, London) it is possible to identify in the first trimester approximately 90 per cent of those women destined to develop pre-eclampsia prior to 34 weeks with a false positive rate of ten per cent.^{4,11} The contribution of each variable to the algorithm accuracy differs; being highest for biophysical factors (MAP, UA PI), moderate for angiogenic factors (PlGF), and lowest for placental proteins (hCG and PAPP-A). However, there is a summative increase in detection rate with the addition of each parameter.^{4,12}

As early onset pre-eclampsia has a low prevalence, the positive predictive value of screening is low (approximately three to six per cent), but the negative predictive value is high (> 99.5 per cent), allowing targeted intervention and improving confidence in the triaging of antenatal care.⁴ The Fetal Medicine Foundation first

trimester screening algorithm for early-onset pre-eclampsia was developed in a high-risk population, but has been validated in low-risk groups.^{4,12} There is little controversy that it performs better than historical approaches in identifying that subgroup of pregnant women at increased risk for pre-eclampsia of early-onset.

What controversy does exist surrounds the efficacy of low-dose aspirin in pregnancies identified at increased risk, as there is healthy scepticism surrounding the ability of aspirin to mitigate the onset or severity of the disease.

Aspirin is a logical therapeutic consideration. In pre-eclampsia there is a functional imbalance between vascular prostacyclin (which inhibits platelet activation and aggregation) and increased thromboxane A2 production (which promotes platelet activation and aggregation). Aspirin irreversibly inactivates the cyclo-oxygenase enzyme required for thromboxane synthesis. Low-dose aspirin therapy is known to be effective in reducing thromboxane A2 production.

The 55 randomised trials involving more than 37 000 women over the past 30 years into the effects of low-dose aspirin in the prevention or amelioration of pre-eclampsia have provided mixed results. Most have shown a modest, but significant, reduction of pre-eclampsia in the treatment group, but the number needed to treat is very large, which has tempered enthusiasm for this intervention. Importantly, the majority of these studies have been hampered by small numbers, multiple study entry points (and therefore timing of intervention), definition changes and multiple study end points.

Recent meta-analyses have shown that in women at high risk for developing pre-eclampsia, daily low-dose aspirin (100–150mg) commenced before 16 weeks reduces the incidence of early and severe pre-eclampsia by between 50 and 90 per cent. The preventative effect is less apparent if aspirin therapy is commenced after 16 weeks.^{13,14}

Caution regarding subgroup analysis from meta-analyses has recently been urged, as these are subject to high false-positive and false-negative results.¹⁵ They should be used for hypothesis generation and then validity tested in separate studies. The systematic review of the effectiveness of low-dose aspirin before 16 weeks is encouraging, but not conclusive. There are small numbers in the trials, raising the possibility that the summary estimates would change significantly with the addition of new data. There is also a tendency to overestimate

treatment effect owing to possible publication bias (where small negative trials are often missing).

There is an understandable concern that as aspirin is a 'blood thinner' and an 'irritant to the stomach' it should be used with caution. Benefits need to significantly outweigh risks. Aspirin is a weak acid absorbed from the stomach and small bowel, is metabolised by the liver and excreted mainly by the kidneys. Small doses have a half-life of approximately 2.0–4.5 hours. The current literature suggests that the use of low-dose aspirin during pregnancy is safe with regard to development of congenital anomalies and also to fetal, neonatal and maternal cardiovascular physiologic states and haemostasis. However, appropriate judgement does need to be exercised in prescribing aspirin prophylaxis to those with a history of bleeding, upper gastrointestinal tract ulcers or taking other medications with which aspirin may interact. It is best avoided in women with active vaginal bleeding and clearly should not be prescribed to women with aspirin allergy. Furthermore, in its recent review of this intervention, the United States Preventive Services Task Force considered there was adequate evidence that low-dose aspirin as preventive medication does not increase the risk for placental abruption, postpartum haemorrhage or fetal intracranial bleeding and does not increase the risk for perinatal mortality.¹⁷ Evidence on long-term outcomes in offspring exposed in-utero to low-dose aspirin is limited, but on first principles is unlikely to be adverse and no developmental harms were identified by 18 months of age in the one study reviewed.

Although some may consider first trimester screening for early-onset pre-eclampsia and aspirin prophylaxis controversial, with the exception of calcium supplementation in women with low calcium intake¹⁶, low dose aspirin is the only drug that can reduce the risk of pre-eclampsia. While there is argument about the magnitude of its effect, it can clearly mitigate the risks associated with the condition while exposing a pregnant woman and her fetus to a considered low risk from the introduction of aspirin. Where aspirin prophylaxis is considered appropriate then, on the basis of available literature, it is arguably preferable to start therapy in the first trimester of pregnancy, or at least before 16 completed weeks of gestation. Consideration of the dosing required to inhibit placental thromboxane, of diurnal rhythms and of other available published data, suggests a dose of 100–150mg per day taken at night is the most appropriate prophylactic regimen.

So, first trimester screening for early-onset pre-eclampsia and initiation of aspirin therapy in those considered at risk. Controversial? Possibly. But given available evidence, in an atmosphere of continuing legitimate academic argument, the judgement was made to offer screening programs in Australia, collect outcome data and publish the results. Women are currently screened in the first trimester of pregnancy using the Fetal Medicine Foundation algorithm for their risk of early-onset pre-eclampsia routinely at the High Risk Obstetric Unit at Royal Prince Alfred Hospital, in Sydney, and by request at Sydney Ultrasound for Women and Monash Ultrasound for Women (subspecialist obstetric imaging practices operating across greater Sydney and Melbourne). In all centres, it is recommended to referring doctors that consideration be given to commencing low-dose aspirin prophylaxis in women found to have a two per cent or greater risk of developing early-onset pre-eclampsia, and for this to be continued until 34 weeks gestation. The local experience is slowly emerging, with Prof Jon Hyett's group at Royal Prince Alfred Hospital having recently published on the accuracy of screening in a low-risk population⁴ and on the therapeutic efficacy of low-dose aspirin in a local setting.¹⁸

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Did you know about the newly established RANZCOG Foundation?

The RANZCOG Foundation has recently been established under the umbrella of the College and brings together the College's various philanthropic activities, including research scholarships, humanitarian aid and the historical collection. As part of this, the operations of the RANZCOG Research Foundation have been transferred to the College's Foundation.

An important change needed to bequests

Should you wish to continue to support the pursuit of *Excellence in Women's Health* through making a gift in your Will, we ask that you amend any reference to 'RANZCOG Research Foundation', replacing it with 'Royal Australian and New Zealand College of Obstetricians and Gynaecologists'.

Bequests are essential for ensuring the work of the RANZCOG Foundation can continue into the future and we thank you in advance for making this required amendment.

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The controversies associated with managing women with a short cervix.

Preterm birth is the leading cause of neonatal mortality and morbidity. Prevention of preterm birth by optimal management of the woman with a short cervix is subsequently a high priority for clinicians. The various causes of preterm birth culminate in a final common pathway of uterine activity and cervical shortening. Consequently, the use of cervix length measurements to aid in prediction of preterm birth has become established. However, aspects of screening, diagnosis and management are debated. We present some of the common dilemmas facing clinicians.

To screen or not to screen?

The Australasian Society of Ultrasound in Medicine advises the cervical length should be assessed at the time of the mid trimester ultrasound.¹ A short

cervix diagnosed in asymptomatic women at the time of routine screening at 20–24 weeks is associated with an increased risk of preterm birth.² Recent data appear to support the use of vaginal progesterone in preventing preterm birth in asymptomatic women with a mid-trimester ultrasound diagnosis of a short cervix. Hassan et al demonstrated, in their randomised controlled trial (RCT), vaginal progesterone reduced preterm birth before 28, 33 and 35 weeks, and 'any neonatal morbidity or mortality event'.³ Controversy exists owing to the resource demands of universal screening and difficulties in standardising cervical length measurement.

How do you measure the length of the cervix?

Cervical length is typically measured by transvaginal ultrasound, after the bladder is emptied, which may deter some sonographers, and pregnant women, from performing the test. There is a lack of agreement among Australian specialists and sonographers on reporting on the cervical length, especially when confusion exists in the presence of prominent cervical mucous or funnelling.⁴ Transabdominal cervical measurement could potentially alleviate the need for transvaginal measurement, but is inaccurate and visualisation of the cervix can be difficult if there is a fetal part overlying the cervix.⁵ The cervical length can be dynamic and change with uterine contraction, fundal or probe pressure, leading to further inaccuracies in the measurement.

When should you place a rescue cerclage?

The decision to place an emergency or 'rescue' cerclage for an open cervix before 24 weeks should be made by an experienced

obstetrician after considering the individual circumstances of the woman. In their guideline, the Royal College of Obstetricians and Gynaecologists (RCOG) cites evidence that rescue cerclage may delay delivery by a further five weeks, compared to expectant management or bed rest alone, and may be associated with a two-fold reduction in preterm delivery before 34 weeks.⁶ Concerns arise regarding the use of a rescue cerclage when faced with symptomatic women. While it is widely accepted that active labour, ongoing vaginal bleeding, premature rupture of membranes and chorioamnionitis are contraindications to cerclage⁶, it can be difficult to be reassured, in the presence of vague symptoms, that placement of cerclage is of more benefit than harm. Furthermore, although studies have shown rescue cerclage prolongs the pregnancy, there is limited evidence that this translates into an improvement in neonatal morbidity or mortality.⁶ Clinicians must also consider if a rescue cerclage keeps a baby in an unfavourable uterine environment or converts a miscarriage to an extremely preterm birth.

What dose of progesterone should be prescribed?

There is a lack of evidence to dictate the best dose and route of administration of progesterone for women with a short cervix. The intramuscular preparation of 17-alpha-hydroxyprogesterone commonly used in the US is not available in Australia. Vaginal progesterone has the perceived advantage of high uterine bioavailability and doses from 90–400mg have been used in studies showing their effectiveness in prevention of preterm birth. One meta-analysis showed no difference in efficacy in preventing preterm birth in studies that used 90–100mg or 200mg doses of progesterone (micronised progesterone or progesterone pessaries).⁷ In the absence of evidence that any dose is superior, local availability of supply and cost should be taken into account when prescribing.

Can a twin pregnancy be managed the same way?

It is tempting to extrapolate that the benefits of cerclage and progesterone recognised in singleton pregnancies complicated by a short cervix will be seen in multiple pregnancies. Contrary to this expectation, a recent Cochrane review demonstrated in a subgroup analysis (with substantial heterogeneity) that women with multiple pregnancy and a short cervix, who underwent an 'ultrasound-indicated cerclage', had an increased risk of low and very low birthweight babies and increased respiratory distress syndrome.⁸ In their guideline, the RCOG cites a number of small studies, including one RCT, that fail to show a benefit for cerclage in twin pregnancies, when making their recommendation against the use of cerclage in twin pregnancy.⁶

The use of progesterone in twin pregnancies complicated by a short cervix is even more controversial. In one meta-analysis, progesterone use in twin pregnancies did not significantly reduce preterm birth compared to placebo, but did reduce composite neonatal morbidity/mortality.⁷ Two further RCTs did not show any benefit of progesterone use compared with placebo in preventing preterm birth in twin pregnancies or twin pregnancies complicated by a short cervix.^{9,10}

Given the lack of evidence for an effective treatment to prevent preterm birth in women with a multiple pregnancy and a short cervix, the value of measuring the cervical length at ultrasound in multiple pregnancies must be questioned. While the knowledge may guide decision-making about the appropriate centre for management or assist in the timing of steroid loading, it may also create an added layer of anxiety for women with an already high-risk pregnancy.

Can cervical pessaries help?

A 2013 Cochrane review of the evidence for the use of cervical pessaries in women with a short cervix included only one RCT of 385 women with a cervix length of 25mm or less who were randomised to cervical pessary or expectant management. The pessary group had a significantly lower rate of spontaneous preterm birth (<37 weeks) compared with expectant management.¹¹ Further research would assist in supporting this finding and guiding clinicians.

Should I prescribe tocolytics?

Much interest exists in tocolytics, in the hope that suppression of uterine activity will prolong pregnancy and prevent the morbidity and mortality associated with preterm birth. In a general population at risk of preterm birth, there is no clear evidence that tocolytic drugs have a significant effect on preterm birth or perinatal or neonatal morbidity.¹² Tocolytics are most widely employed to attempt to delay delivery for the purpose of in-utero transfer or steroid loading.

What about bed rest?

It is tempting to restrict women with a short cervix to bed rest in the hope that reduced activity and favourable gravitational forces will prolong the pregnancy. Unfortunately, evidence is lacking to support this notion and, in fact, some evidence exists to the contrary. One retrospective cohort study of women with a short cervix demonstrated 40 per cent of patients in the cohort were advised activity restriction and this same group had a higher number of preterm births compared to the cohort who were not advised to restrict activity.¹³ It is recommended to consider not only the woman's individual circumstances, but also the potentially detrimental social, medical and economical impacts such a management strategy may have.⁶

Inpatient versus outpatient management

Further controversy exists about whether a woman with a short cervix should be allowed to be managed at home, when at risk of potential preterm birth. While bed rest is not recommended, it is possible that inpatient admission, with mobilisation privileges, could lead to better outcomes through immediate access to obstetric and neonatal care. Contrary to this hypothesis, a retrospective cohort study on hospitalisation in women with a short cervix showed that hospitalisation was an independent risk factor for cervical shortening, was associated with increased risk of earlier delivery and a shorter time from diagnosis to delivery.¹⁴ Further research is required to guide clinicians. It is also necessary to consider the woman's gestation, comorbidities, resources available at the closest hospital and ability for timely access (which can be influenced by transport, distance from hospital, support people at home) when arranging the location of care.

Is it okay to have sex?

The effect of intercourse in women with a short cervix has not been rigorously studied with RCTs. In term patients, there is evidence that intercourse does not increase the rate of spontaneous onset of labour, as demonstrated by an RCT of women awaiting

induction of labour at term.¹⁵ It is difficult to infer similar outcomes in preterm women with a short cervix, so advice should be individualised in the absence of guiding evidence, accounting for patient factors and preferences.

Conclusion

Clearly, there are many areas of uncertainty in the management of women with a short cervix. Hopefully, continuing research in this area of interest will help to guide future practice. In the meantime, it is important to individualise the care for the woman, taking into account her personal history and circumstances.

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Telling the future



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The limitations of the predictive tests currently available to assess threatened preterm labour.

In terms of a diagnostic quandary, threatened preterm labour continues to vex us. We have all assessed an anxious woman presenting with uterine activity and the price of making the wrong diagnosis at early gestations is high. In 2012, 5456 infants in Australia and New Zealand were born before

34 weeks, representing only 1.7 per cent of the total births, but a huge cost in terms of morbidity, long-term health consequences and inevitably neonatal care dollars.¹ However, as few as three per cent of the women who present for attention have been found to progress to delivery within the seven ensuing days in some studies.²

In the absence of clear cervical dilatation or another clinical factor, clinical prediction of which women will deliver is poor. However, sending our patient home runs the risk of false reassurance and a potentially avoidable adverse outcome. Cautiously admitting for observation will be complicated by available neonatal facilities and the need to transfer to urban tertiary centres, with considerable costs to the healthcare system and disruption to family life. In addition, steroids and other antenatal interventions such as magnesium sulphate and antibiotics are critical if delivery is imminent, but expensive and potentially harmful if given without clear indication.

There are two commercially available and competing tests for biomarkers of the pre-labour cascade in Australia and New Zealand: fetal fibronectin (fFN) and Actim Partus. Controversy exists over which is the better test and, in practice, both tests have drawbacks.

The fFN was developed first and extensively validated in clinical trials involving more than 40 000 women in excess of 200 peer-reviewed studies. This is in contrast to the Actim Partus, which has been trialled in fewer than 3000 women in fewer than 30 studies. The fFN therefore paved the way to clinical acceptance, and continues to be the more widely used technology, aided by FDA approval in the US, which Actim Partus has not gained.

The two tests are not however equivalent, although the detection of significant levels of either between 22 weeks and 35 weeks is thought to indicate chorio-decidual separation, regardless of the underlying precipitating mechanism. Fetal fibronectin is an adhesive glycoprotein produced by many cell types, including the fetal amnion. The Actim Partus is an immuno-chromatographic bedside test for phosphorylated insulin-like growth factor binding protein (IGFBP-1) produced by the decidua. The swab specimen collection techniques are also slightly different – the fFN can be collected from the posterior vaginal fornix, but the Actim Partus is potentially more technically challenging and uncomfortable, requiring the removal of fluid from the external cervical os.

Both tests are obviously subject to false positive results, as a background low level of these markers will always be present upon swabbing cervico-vaginal secretions and an increase is not specific for labour. Both tests will usually give false positive results in the presence of amniotic fluid and significant blood. The fFN test can also turn false positive in the presence of semen and lubricating jelly or recent cervical trauma (although a negative result is still valid as a true negative), and false negative results have been obtained owing to Candida vaginal infection. Actim Partus is marketed as able to be used regardless of recent intercourse since IGFBP-1 is not present in semen, but interestingly the product information states there is no data currently to support these assumptions and recent vaginal examination can cause a false negative by removing fluid from the cervical os.

The fFN is currently available in three different modalities: the original TLI-iq qualitative test; the recently released quantitative 10Q Rapid fFN Analyser; and the quantitative QuikCheck fFN, which is a bedside dipstick test retailed for AU \$124 per test. The TLI-iq has the slowest turnaround time of 25 minutes and has therefore been phased out by the company in Australia, but is still used in New Zealand. The replacement quantitative 10Q, available in both countries, is designed to be kept in labour wards as opposed to in a laboratory and only takes ten minutes to process. It costs around AU \$104 per test processed, but requires an analyser (\$4000) and personnel to run daily calibrations. Quantitative results have also

Table 1. The only published trials directly comparing clinical performance of fetal fibronectin and IGFBP-1 testing in the same high-risk patients.

Study	NPV		PPV		Sensitivity		Specificity	
	FFN	AP	FFN	AP	FFN	AP	FFN	AP
Turnell et al 2005 ³	99	99	22	16	80	80	85	78
Ting et al 2007 ⁴	89	92	39	46	61	72	78	80
Eroglu et al 2007 ⁵	97	97	35	41	83	83	81	84
Audibert et al 2010 ⁶	98	91	36	20	83	17	84	93
Cooper et al 2012 ⁷	88	86	54	22	33	39	95	74
Khambay et al 2012 ⁸ (asymptomatic women)	79	70	67	0	-	-	-	-
Average	92	89	32	24	68	58	85	82

Table 2. The meaning of the statistical terms used to describe the accuracy of a predictive test for pre-term labour.

Statistical term	Definition
Negative predictive value	The percentage of women with a negative test who will not deliver within 7–10 days
Positive predictive value	The percentage of women with a positive test who will deliver within 7–10 days
Sensitivity	The percentage of women who will deliver within 7–10 days who are correctly identified 'positive'
Specificity	The percentage of women who will not deliver within 7-10 days who are correctly identified 'negative'

been studied as allowing stratification of risk, since the positive predictive value rises with the concentration detected, and fFN has been validated in combination with cervical length screening for asymptomatic women at high risk of pre-term labour.²

The Actim Partus test's major market advantages were the lower cost (AU \$40 per test) and avoidance of the need for an analyser, particularly in a small unit that may only see a few cases a year. The second advantage is less clear-cut now that an equivalent analyser-free fFN test is available and the fFN company will now place an analyser in a hospital free of charge on an equipment loan agreement.

The cost advantage does, however, need to be weighed up against the clinical utility of the test, which is hard to do given the paucity of published data for the Actim Partus test. In symptomatic women, the fFN has a generally better negative predictive value of 88–99.5 per cent overall, compared to 86–95 per cent for Actim Partus. There have only been six studies published directly comparing the two tests in the same high-risk women, of which one trial was performed in asymptomatic patients (see Table 1). The trend of these studies suggests that, although generally comparable, the Actim Partus performs slightly less well over all parameters, particularly in asymptomatic women with a positive predictive value of zero per cent. This equates to a small saving from using a cheaper test potentially negated by a much larger unnecessary cost of admitting and transferring women to tertiary units who will not deliver.

Small-scale studies have described a cost saving when using the fFN test, in the order of an average of AU\$3000 per patient tested in an Australian study.⁹ Larger scale cost-benefit reviews have not taken into account societal costs of admitting women to hospital in terms of lost productivity or childcare costs.^{10,11} In reality, the on-the-ground advantages, and possibly visible marketing strategies, have led to widespread uptake of these tests in Australia, New Zealand, Canada, the US and Europe.

Both tests are currently undergoing Medical Services Advisory Committee review in Australia; the Actim Partus for the first time, since the clinical implementation of the Actim Partus has to date relied on the groundwork prepared by 20 years of fFN research and the assumption of equivalent validity. Based on the data so far, the Actim Partus test should not be used in asymptomatic high-risk women and may result in more unnecessary intervention owing to a lower positive predictive value. The current value of both tests lies in the high negative predictive values, allowing up to 90 per cent of symptomatic women to be reassured and discharged. A positive result requires further assessment in a tertiary setting, preferably with ultrasound assessment of cervical length, which has been shown to perform better than either test, to guide ongoing management.

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Caesarean on request

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Elective caesarean section for maternal request remains a contentious issue, with many women wishing to avoid a vaginal birth and many hospital administrators, clinical directors and patient advocate groups continuing to push for a lower caesarean section rate.

I was surprised, like most other obstetricians, when in 2011 the UK National Institute for Health and Care Excellence (NICE) guidelines group reviewed the evidence and found that caesarean section for maternal request was not unreasonable.¹ They concluded that, with appropriate counselling regarding the risks and benefits of elective caesarean section and psychological support if required, a planned caesarean section should be offered to a woman who requests it. Conscientious objectors to caesarean sections for maternal request should refer obstetric care onto an obstetrician who is willing to carry out the caesarean if they are uncomfortable acceding to the woman's request. So, what are the risks and benefits of elective caesarean section for maternal request?

Benefits

Pelvic floor

A 2013 study by Gyhagen et al of followed up 5000 Swedish women over a period of 20 years, who had only one child either vaginally or by elective caesarean section², found that primary caesarean section was significantly protective against both urinary incontinence and symptomatic pelvic organ prolapse. The prevalence of urinary incontinence of more than ten years duration was 2.75 times greater after vaginal birth at 10.1 per cent, compared with 3.9 per cent after caesarean section. Urinary incontinence was also more common 20 years after vaginal birth (40 per cent) than after caesarean section (28.8 per cent).

Of the same 5000 women, those who delivered vaginally had a significantly higher prevalence of symptomatic pelvic organ prolapse at 14.6 per cent, compared to 6.3 per cent in those delivering by caesarean section. Interestingly, this study also found a three per cent increase in symptomatic pelvic organ prolapse for every 100g increase in birthweight over 3000g.

The 2013, 12-year follow-up of 10 000 women by the ProLong Study group reported similar benefits of caesarean section, with 29 per cent of women delivering vaginally having prolapse to the hymen or beyond, compared with only five per cent of women delivering exclusively by caesarean section.³

Faecal incontinence may have a more multifactorial origin than we think, as the 12-year follow-up revealed a 3.7 per cent incidence in women delivering exclusively by caesarean section and four per cent in women having a normal vaginal delivery (NVD).⁴

In summary, a woman can more than halve her chances of pelvic organ prolapse or urinary incontinence for more than ten years duration by delivering her babies exclusively by caesarean section.

Early postpartum haemorrhage

In their summary of the available evidence, the NICE group quoted a comparison of planned vaginal birth (which includes instrumental vaginal deliveries and emergency caesarean section) with elective caesarean section and found that the elective caesarean group had a lower incidence of postpartum haemorrhage (PPH) (1.1–3.9 per

cent) compared with 6–6.2 per cent in other births. Obstetric shock was also three-fold lower at 0.006 per cent versus 0.018 per cent.

These findings are supported by the 2013 blood transfusion rates at National Women's Hospital (NWH) in Auckland, where transfusion in elective caesarean section was required in 1.2 per cent of cases, less than half of that of planned vaginal birth (2.7 per cent).⁵ For actual vaginal birth the transfusion rate was still higher than elective caesarean section at 2.1 per cent. This is despite planned caesarean sections including indications associated with high intra-operative blood loss, such as placenta praevia and accreta.

Predictability and safety

A planned caesarean section offers a more predictable birth than a planned vaginal delivery. An elective caesarean section at NWH for a first baby will avoid: the 25 per cent chance of an emergency caesarean section; the 20 per cent chance of an instrumental vaginal birth; the 25 per cent chance of an episiotomy; the three per cent chance of a third-degree tear; and the possibility of having to go to theatre after a normal birth for manual removal of the placenta.⁶

The NICE appendix includes one report that found elective caesarean delivery at 39 weeks reduced perinatal mortality by one per thousand births, presumably by avoiding an at term stillbirth. However, another report in the same appendix showed an increase in neonatal mortality in the caesarean section group. I believe this is likely to be owing to not controlling for high-risk pregnancies and fetal abnormalities, as the majority of term stillbirths in NWH are still related to congenital abnormality.

Psychological

Some patients are referred to our private practice having been so traumatised by previous vaginal birth experiences that they have only planned another pregnancy after establishing it is possible to have an elective caesarean section. These women invariably find caesarean section a very positive birth experience. Other reasons for requesting a caesarean section include a past history of sexual abuse and a fear of childbirth. For some women, the mode of birth is negotiable with appropriate psychological support and the promise of an early epidural. Other women, regardless of support will still request a caesarean.

While almost all of my patients will acknowledge the convenience of knowing the date and approximate timing of their baby's arrival, in my experience this has rarely been an indication on its own.

The risks

Recovery

Recovery is longer than after a normal vaginal birth, with NICE reporting an average postnatal stay 0.6–1.4 days longer. There are no data given on return to normal daily activities, such as lifting or driving, but experience and anecdotal evidence would support a longer recovery time from caesarean section overall. Of interest, many of my patients with a bad vaginal birth experience (such as

third-degree tears) find their recovery significantly easier after an elective caesarean section.

The doubling of hysterectomy for PPH and the five-fold increase in cardiac arrest in the elective caesarean group reported in the NICE guidelines are unlikely to affect a low-risk patient without a praevia, accreta or cardiac condition. However, repeated caesarean section is likely to increase the risk of both a placenta praevia and accreta. The background risk of accreta has been reported to be 1:400 and this increases to 1:300 after two caesareans, 1:200 after three, 1:50 after four, 1:40 after five and 1:15 after six caesareans.⁶

Clearly, there is an increasing likelihood of complications with subsequent caesarean sections and my patients tell me that apart from the quicker recovery after elective compared to emergency caesarean section, the recovery is no easier with subsequent caesareans. This is unlike vaginal birth, where the second and subsequent births are almost invariably easier and less complicated than the first birth. The practical implications of having to deal with a toddler while recovering from a caesarean have prompted many of my patients to request a trial of labour for subsequent pregnancies.

NICE report some studies showing fewer deep vein thromboses (DVTs) associated with elective caesarean section than NVD. However, other studies still show an increased thromboembolic risk with caesarean section, rendering these trends inconclusive.

Costs

The most expensive birth is an after-hours, in-labour emergency caesarean section, where both delivery unit and on-call theatre staff and facilities are used. Indicative costs for birth in the USA in 2011 were⁷:

• Normal Vaginal Delivery (NVD)	\$10 657
• Assisted Vaginal Delivery (AVD)	\$13 749
• Planned CS	\$17 859
• Emergency CS	\$23 923

Based on the NWH rates of NVD (55 per cent), a 20 per cent AVD rate, and a 25 per cent emergency LSCS rate, 100 planned vaginal births would cost \$1,399,000 and 100 planned caesareans would cost \$1,785,900. Comparing planned vaginal births, rather than actual vaginal births, with elective caesarean section there is only a 28 per cent increase in costs compared to the 78 per cent extra cost if a simple crude comparison is made.

Effects on the neonate

When comparing planned vaginal birth with elective caesarean section, the results from a study reported in the NICE guidelines shows a significant increase in the NICU admission rates at 6.3 per cent and 14 per cent, respectively. This is compared to the NWH 2013 annual clinical report findings that showed the NICU admission rate for planned term vaginal births was 5.5 per cent compared to 8.2 per cent for elective caesarean section. Surprisingly, the NICE study showed no significant difference in neonatal respiratory morbidity between the two groups (RR 1.04).

Differences in neonatal gut flora between babies born by caesarean and vaginally have been shown.⁸ There are postulated benefits of reductions in asthma, type 1 diabetes mellitus, obesity and allergies with exposure to and acquisition of the maternal vaginal flora.⁹ Caesarean section has also been shown to affect early breastfeeding success, but there is no difference in breastfeeding rates at six months when comparing modes of delivery.¹⁰

Summary

The majority of women who have a normal vaginal birth will not have either prolapse or incontinence and will have a quicker recovery than women who have a caesarean. However, for the 40 per cent of women experiencing urinary incontinence 20 years after childbirth, one in four of them would not have their symptoms if they had had a caesarean.

In an ideal world, birth would either be an uncomplicated vaginal birth and or an elective caesarean, this would result in optimum outcomes for both individual women and the health budget. The challenge for us as clinicians is being able to assess whether a woman is likely to have an uncomplicated normal vaginal birth or would be better suited to an elective caesarean section.

Although there is no evidence in the literature to suggest we can predict successful vaginal birth, we should take note of the importance of birthweight in predicting prolapse, with each 100g over 3000g increasing the risk of prolapse by three per cent. Perhaps we obstetricians are better than we think at predicting uncomplicated vaginal birth, as the third- and fourth-degree tear rate for private specialists of 1.4 per cent is half the overall rate of 2.9 per cent at National Women's Hospital, where 48 per cent of the births are booked with a private midwife.

If a woman is planning on having three or more children, I believe she would be wise to try to give birth vaginally. However, for one or two children then a very serious case for delivery by elective caesarean section can be made. Ultimately, the woman should make an informed decision that she is comfortable living with for the rest of her life.

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Should inductions be pushed?

Agnes Wilson PhD
Guideline Co-ordinator

The latest clinical evidence suggests perhaps more labours should be induced.

A/Prof Stephen Robson
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The Australian National Maternity Services Plan¹, published by the Australian Health Ministers' Conference in 2011, provided a five-year vision: 'All Australian women will have access to high-quality, evidence-based, culturally competent maternity care in a range of settings close to where they live.' The document stresses that woman-centred maternity care is responsive to women's needs and preferences, and enables them to access objective, evidence-based information that supports informed choices about their maternity care.

The National Maternity Service Plan offers plaudits – '[Australia] is now one of the safest countries in the world in which to give birth or to be born' – but it also notes, 'although the majority of Australian women have vaginal births, there appears to be a trend away from normal birth...Australia has high rates of birth by caesarean section compared with the OECD average.'

An issue singled out for particular criticism in the document is induction of labour (IOL): '...forms of intervention, including induction of labour, are also high: 25.3 per cent of mothers had an induced labour in 2007, while a further 20 per cent of all mothers had an augmented labour...The rise in interventions, including the reason and their impact on women, babies, and the health system, is the subject of considerable debate...'

So what's all the fuss about? Labours are generally induced when the risks, to either mother or baby, associated with continuing a pregnancy seem to be greater than those of delivery. For the purposes of benchmarking, the Australian Council on Healthcare Standards (ACHS) previously used a number of 'defined' indications for induction in its clinical indicators: diabetes, premature rupture of membranes, hypertensive disorders (including chronic renal disease), fetal growth restriction, isoimmunisation, fetal distress, fetal death, infection and prolonged pregnancy. Such lists are, however, designed for large-scale benchmarking and are by necessity rather narrow and there are obviously many more reasonable indications for IOL. The UK National Institute for Health and Care Excellence (NICE) guidelines on IOL make the following observation:

Although a variety of specific clinical circumstances may indicate the need for induction of labour with a greater or lesser degree of urgency, the essential judgement that the clinician and the pregnant woman must make is whether the interest of the mother or the baby, or both, will be better served by ending or continuing the pregnancy. In making the judgement, it is necessary to factor in the attitude and wishes of the woman in response to her understanding of the actual risk of continuing the pregnancy, as well as the possible consequences of the method employed and the response to the induction of labour.²

Over the last 20 years in Australia, the proportion of labours that are induced has increased from 21.6 per cent in 1991, to 32.2 per cent in 2011 (OR 1.72, 95 per cent CI 1.70, 1.74. $P < 0.05$).^{3,4} National data detailing the primary indications for IOL have only been published since birth year 2006⁵, and although there have

been statistically significant changes over the five years, it is possible that these represent changes in reporting rather than true shifts (see Table 1). It is also important to bear in mind that IOL is commonly undertaken for a combination of reasons rather than one single indication, and this type of decision-making is very difficult to capture in mandated jurisdictional data collections.

What does IOL achieve?

Going to the trouble of inducing labour suggests that it ought to yield some tangible benefit and in Australia at present almost one-third of women who attempt vaginal birth have their labours induced.⁴ That's a lot of effort. Few would argue that perinatal conditions such as hypertensive disorders, diabetes, infection, and concerns about fetal growth and wellbeing (which together constitute more than one third of inductions^{4,5}) are unequivocal reasons for delivery. What about prolonged pregnancy? What about 'social' induction?

Many public hospital maternity services face great pressures in running their birth suites. Experienced midwifery staff are expensive to employ, difficult to roster equitably and safely, and indeed it can be difficult to actually find enough suitable staff. Hospitals also face challenges in providing a physical infrastructure with enough rooms and beds to meet demand. There is commonly an institutional 'attitude' against what are often called 'soft' indications for induction. All of these issues are important and need to be carefully considered. There would have to be very good reasons to consider adding even more inductions to already over-stretched maternity services.

For a generation of midwives and doctors, it was an article of faith that routine IOL in an 'uncomplicated pregnancy' any earlier than 41 weeks (and often longer) was of no benefit to the mother or baby. Patient information commonly includes statements such as:

Studies show that babies may be at an increased risk of stillbirth after 42 completed weeks ... This risk is small for women with a healthy pregnancy and no other risk factors ... induction of labour will be offered after you are 10 days overdue. You may choose not to have your labour induced...[if] you do not want to have an

Table 1. The commonest reasons for induction of labour in Australia. Data extracted from references 4 and 5.

Indication for IOL	Birth year					
	2006	2011	OR	95% CI	CI	P Value
Prolonged pregnancy	30.1%	23.3	0.70	0.69	0.72	<0.05
Prelabour ROM	10.4%	13.0	1.39	1.24	1.33	<0.05
Hypertension/PE	10.9%	10.0	0.89	0.86	0.93	<0.05
Suspected IUGR	4.0%	4.7	1.18	1.11	1.25	<0.05
Other*	27.8%	36.7	1.50	1.47	1.54	<0.05

*The category 'other' does not include diabetes, perinatal death, fetal distress, isoimmunisation, and chorioamnionitis.

induction of labour, we recommend that you have an ultrasound scan to assess the well-being of your baby... There is every chance you will go into labour spontaneously prior to 42 weeks or prior to a booked induction...

Patient information such as this is written from a perspective of patient autonomy – that patients have the right to make decisions about their medical care without their ‘healthcare provider’ trying to influence their decisions. However, with rights come responsibilities and it is important that ‘healthcare providers’ actually provide accurate information.

Perhaps the most important thing that women and their families, and indeed maternity services in general, need to understand is that major differences exist between women of different ages. As stillbirth authority Dr Ruth Fretts expressed last year, in the pages of *O&G Magazine*:

Both maternal age and parity are significant risk factors in the rates of late pregnancy loss. In a large US study by Reddy et al, they found the most notable difference between younger and older women occurred after 38 weeks gestation. At 39 weeks, the risk of stillbirth for women 40 years of age or older was the equivalent to that of younger women (less than 34 years of age) who reached 41 weeks of gestation. This effect was modified by primiparity, with the risk of a stillbirth after 37 weeks of pregnancy with multiparous women young than 35 having the lowest risk 1.29/1000 per ongoing pregnancies, whereas the risk for a primiparous women 40 years of age or older was 8.65/1000 ongoing pregnancies (a 6.7 fold difference).⁶

Over the last two decades, the proportion of women aged 40 or more having babies in Australia has more than tripled (OR 3.0, 95 per cent CI 2.9, 3.1, $p < 0.05$).^{3,4} Indeed, there has been an enormous shift in age distribution of women having babies: the number of births to women aged 35 or more has increased by an additional 150 per cent (OR 2.4, 95 per cent CI 2.36, 2.44, $P < 0.05$) since 1991.^{3,4}

The most recently published systematic review and meta-analysis⁷, reviewing randomised controlled trials in which IOL was compared with either placebo or expectant management among women with a viable singleton pregnancy, revealed a startling finding. More than 30 000 women had participated in more than 150 individual trials, and the risk of caesarean delivery was 12 per cent lower with labour induction than with expectant management, with a pooled relative risk of 0.88 (95 per cent CI 0.84, 0.93), a significant result at both term and post-term gestations. Furthermore, the authors found that the initial cervical score, indication for induction, and method of induction did not alter the main result. Their analysis also revealed a reduced risk of fetal death (RR 0.50, 95 per cent CI 0.25, 0.99) and admission to NICU (RR 0.86, 95 per cent CI 0.79, 0.94). The conclusion was that caesarean section rates were lower among women undergoing IOL than among those managed expectantly from term onwards, with additional benefits for the fetus. This completely turns the traditional paradigm on its head.

Two years before, Stock and colleagues had reported the results of a study of more than a million singleton pregnancies of 37 weeks or more from the UK.⁸ They compared the outcomes of ‘elective’ IOL (which they defined as IOL with no recognised medical indication) with those of expectant management, and compared outcomes such as perinatal mortality, mode of delivery, postpartum haemorrhage, obstetric anal sphincter injury, and admission to NICU. Adjustment



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was made for the women's age at delivery, parity, year of birth, birthweight, deprivation category, and, where appropriate, mode of delivery. They found that, at each gestation between 37 and 41 completed weeks, elective IOL was associated with a decreased odds of perinatal mortality compared with expectant management, but no reduction in the chance of a spontaneous vertex delivery.

Where to from here?

The Australian National Maternity Plan¹ takes as its linchpin the principle that, 'maternity care should be evidence-based and woman-centred, and acknowledge pregnancy, birth and parenting as significant life events for women.' It is completely unrealistic to dismiss the broader range of perceptions and expectations around IOL, pertaining to women, midwives, doctors and hospital administrators, as well as the community in general.

One of the main causes of 'access block' for many maternity services is that women recovering from caesarean section spend longer in hospital than women who have a vaginal birth. A perception that IOLs tie up staff and birthing rooms, and that 'failed' IOL is a major contributor to caesarean section rates will naturally cause anxiety to maternity staff and administrators. For this reason, many women and their families are given the impression that a request for IOL is selfish and risky, even if the impression is given inadvertently.

If it were true that a liberal approach to IOL increased the rate of caesarean section or led to worse outcomes for babies, then these would be completely legitimate concerns. Caesarean birth obviously influences the mode of delivery in the next pregnancy and may limit family size. Downstream, the risk of abnormal placentation increases after three caesarean sections. Babies who suffer from complications after birth incur higher costs for their care and admission to a NICU or SCBU may mean mothers spend more time as maternity inpatients, even if they are not delivered by caesarean section.

However, these fears appear to be unfounded. Indeed, the best evidence we have for the current demographic profile of women having babies in Australia, is that a low threshold for IOL at term actually reduces the risk of caesarean section quite substantially.⁷ Similarly, babies seem to be less likely to suffer ill effects, including the disaster of stillbirth.⁸

Should more labours be induced?

As the National Maternity Plan¹ emphasises, it is critical that women and their families be engaged in decision-making about their birth. There is a symbolism associated with birth that is rarely present in other areas of hospital activity, with the exception perhaps of palliative care. Maternity care providers commonly have strongly held views that have to be taken into account. Furthermore, birth care is expensive, with extensive resourcing required in terms of staffing and physical infrastructure. When things don't go to plan, adverse maternity outcomes often expose services to embarrassing publicity and costs, and can have a severe effect on morale within a unit. For all of these reasons, it can be very difficult for clinicians and administrators – at both a local and a jurisdictional level – to steer a course with which everybody is happy.

When guidelines are being developed for clinical care within maternity services, it is critical that a balance be struck that will optimise outcomes for women and their babies. The available evidence supports a relatively liberal consideration of IOL at term, and it may be that the current policies in many units are actually contributing to the very problems that people are struggling to solve.

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The fetal ECG ST waveform



Dr Henry Murray
FRANZCOG

The fetal ST interval changes if the fetus suffers oxygen deficiency. ST analysis, therefore, promises to highlight those changes and expedite delivery of the hypoxic fetus. Does it work?

Despite guidelines for the use and interpretation of cardiotocographic (CTG) traces in labour, outcomes in some units still do not match the wish to deliver all neonates unaffected by intrapartum asphyxia. Some guidelines, like those of the UK's National Institute of Health and Care Excellence (NICE) 2007¹, are designed to annotate anomaly

and appoint risk, while others use a likelihood scale for the risk of fetal acidaemia. All rely on a definitive diagnosis of acidaemia being provided by fetal scalp blood sampling, which is variably available in units owing to expertise and equipment issues. Since the advent of CTG monitoring in labour, various groups have attempted to improve on the fetal heart rate monitoring with the development of other technologies, one of which is analysis of the fetal electrocardiographic (FECG) waveform.

A chance tracing of the FECG was first made in 1906, when Cremer was recording the ECG of a pregnant woman using a very primitive string galvanometer.² Over the next 50 years, many attempts were made to obtain a reliable and reproducible recording of the FECG, but all were thwarted by poor signal quality and electrical interference that obliterated all but some of the QRS complexes. Even the advent of the fetal scalp electrode failed to give a clear and usable signal, owing to the noise associated with the second electrode (see Figure 1). Some tried placing the second electrode in places like the vagina and even the rectum, but (fortunately) this did not improve the signal over that placed on the leg. Others tried electrical filters to deal with the unwanted interference, but they destroyed the recording of the low frequency P and T waves. Still others successfully used averaging of the signals in a technique, where the R waves of successive heart beats were aligned electronically to produce a single waveform on a computer screen every four, six or fifteen beats. This resulted in the regular P and T waves of the complexes being visualised while the random electrical noise on the trace was diminished. The clarity of the waveform was improved by

adding more and more complexes to an average, but herein lies an important problem. If the PR or ST intervals varied (see Figure 2), the P and T waves would not align exactly as each successive waveform was added to the average. Hence, for any given T wave height measured at a steady heart rate, the averaged waveform T wave height would fall in the recorded averaged complex if the heart rate rose or fell, given that the ST interval varies with heart rate, even though the actual T wave height did not change.

So, where does this leave the FECG waveform and, in particular, the measurement of the T wave? In 1987, Greene showed in the fetal sheep that ST segment and T wave elevation occurred during moderate and severe hypoxia.³ A microprocessor-based system was developed⁴ to measure these changes using averaging of the ECG waveform around the R waves. The ST waveform changes were measured as the ratio of the T wave height/the QRS complex height, called the T/QRS ratio.

Sheep data showed a rise in the T/QRS ratio occurred not only to fetal asphyxia, but also to an infusion of isoprenaline (an adrenaline analogue) in the normoxic fetus. The T wave changes in asphyxia were reported to be not due to the effects of adrenaline on the heart as the T wave remained elevated in the presence of propranolol a beta blocker.⁸ The T wave changes in fetal asphyxia are attributed to myocardial glycogenolysis and metabolic acidosis. If that is not confusing enough, a further T wave change was seen in 'acute hypoxic stress' where the T wave was seen to become biphasic and not increase in height.⁶

In the face of the understanding that T wave changes in the fetus can occur in the normoxic and hypoxic fetus and those changes are not uniform depending on the acute nature of any fetal hypoxia, the advent of a commercial ST microprocessor (STAN, Neovanta Medical AB) still led to the development of randomised clinical trials in humans. The trials were to look at the CTG + T/QRS versus CTG +/- fetal blood loss sampling (FBS) alone with the outcomes being caesarean section rates, operative vaginal delivery rates, cord metabolic acidosis, neonatal encephalopathy, admissions to special care unit and the need for fetal scalp blood



Figure 1. A typical ECG signal obtained from a fetal scalp electrode. The bar equals one second.

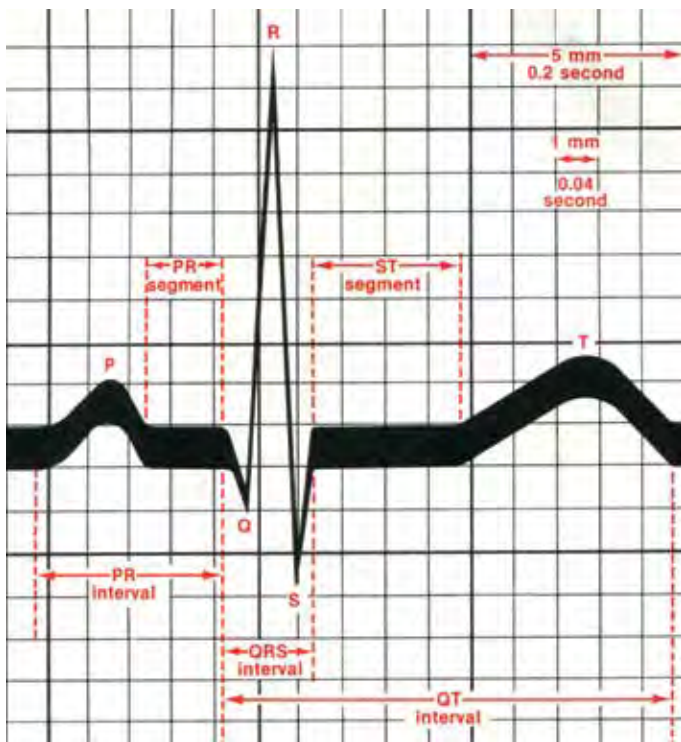


Figure 2. The ECG waveform.¹¹

sampling. In the early phase of the human studies, one trial was investigated for the accusation of scientific fraud by Lund University, Sweden (see Figure 3).

The parameters for recording the T/QRS are strict:

1. Given that a T wave rise can occur in the face of fetal stress or hypoxia and that the normal baseline height varies from fetus to fetus, recording of the T wave in any labour has to begin before any rise in T wave has occurred in order for it to be appreciated. This means the membranes have to be ruptured and the scalp electrode applied in early labour, and preferably before any CTG anomaly has occurred.
2. Given that the T wave can respond to innate fetal adrenaline, which can vary even in normoxia, any T/QRS change has to be related to the fetal condition as defined by the CTG. The CTG classification used for the clinical trials is the FIGO classification, which differs from both the NICE and RANZCOG classifications. No T/QRS change is considered significant in the face of a normal CTG – which presupposes the CTG can be correctly interpreted.

3. Recordings can only be made if the fetus is ≥ 36.0 weeks gestation given 'preterm fetuses may have underdeveloped endocardial-epicardial inter-phase that may interfere with signal conduction'⁹, a statement for which it is difficult to find extensive evidence.
4. Recording cannot occur in a fetus 'with structural or functional cardiac anomaly'.
5. Recording necessitates membrane rupture and application of a scalp electrode, eliminating those in whom an electrode is contraindicated.
6. Recordings should not be ceased (even if the CTG is normal) in order not to miss a T/QRS change.
7. If the fetal signal is poor and the T/QRS cannot be recorded, the CTG analysis should revert to that of the NICE guideline.

Once applied, the recording of the T/QRS ratio requires a number of algorithms to be followed. The first is the four Cs: check that case is appropriate; classify the CTG (the main issue that dogs the use of the CTG and why we wanted a different technology in the first place); correlate the observed T wave changes with the CTG to determine any significance; and cascade for timely and appropriate intervention.⁹ The algorithm for management of a T/QRS change is given in Figure 4.

Clinical experience has led to some revision of the guidance.⁹ Of particular concern is: 'Abnormal CTG pattern for more than 60 minutes, or less if the FHR deteriorates rapidly, with normal ST requires qualified assessment and checking for non-deteriorating fetal state'. I think this means: if the CTG is abnormal but the T wave has not risen, check according to the CTG not the T wave. Why might the T wave not rise in fetal compromise? Possibly the decelerations are lowering the recorded T wave height owing to the averaging issue mentioned earlier, possibly some fetuses function at a maximal adrenergic drive and the T wave does not change with increasing hypoxia.⁷ So that may explain the acknowledged five per cent false negative rate of T/QRS detection of fetal hypoxia. Why might there also be an acknowledged five per cent false positive rate? A fetus with typical variable decelerations and a normal pH can raise adrenaline as a response to the cord compression.⁷

The revision also indicates that intervention in response to the T/QRS changes indicating asphyxia should be in the form of delivery within 20 minutes in first stage and ten minutes in second stage, a limiting feature in many units.

So much for the limitations. What were the Cochrane metanalysis¹⁰ outcomes for the trials of CTG+ T/QRS versus CTG +/- FBS

Press release: Inquiry into research fraud completed

22 October 2008

Inquiry into research fraud completed

In May 2007 a case of alleged research fraud was reported to the Vice-Chancellor of Lund University, Göran Bexell. The report concerned suspected irregularities in a study of a technology for fetal monitoring, known as STAN (ST analysis of fetal ECG). An inquiry conducted by an external investigator now draws the conclusion that data were manipulated in the study. The Vice-Chancellor has therefore decided that the study should be subjected to further inquiry.

Figure 3. Press release from Lund University suggesting scientific fraud.

	Intermediary CTG	Abnormal CTG
Episodic T/QRS-rise (duration shorter than 10 min)	Increase greater than 0.15 from baseline	Increase greater than 0.10 from baseline
Baseline T/QRS-rise (duration at least 10 min)	Increase greater than 0.10 from baseline	Increase greater than 0.05 from baseline
Biphasic ST (a component of the ST-segment below the baseline)	Continuous longer than 5 min or >2 episodes of coupled Biphasic ST type 2 or 3	Continuous longer than 2 min or >1 episode of coupled Biphasic ST type 2 or 3

Figure 4. STAN clinical guidelines: ST-changes that prompt clinical intervention.⁶

alone in labour? Five trials with 15 338 women show no significant difference in the:

- LUSCS rate, (RR 0.99, 95 per cent, CI 0.91-1.08);
- rate of neonatal metabolic acidaemia (RR 0.78, 95 per cent, CI 0.44-1.37); and
- neonatal encephalopathy (RR 0.54, 95 per cent, CI 0.24-1.25).

Of significance was:

- fewer blood scalp samples in labour (RR 0.61, 95 per cent, CI 0.41-0.91);
- fewer operative vaginal deliveries (RR 0.89, 95 per cent, CI 0.81-0.98); and
- fewer admissions to SCBU (RR 0.89, 95 per cent, CI 0.81-0.99).

Unfortunately, the ST waveform does not fulfil the wish to have a technique that results in the reliable detection of intrapartum asphyxia over that of the CTG. Further data for the meta-analysis will, I am sure, be welcome, but the requirements of the technique, including membrane rupture and FSE application, and the five per cent false positive and negative results, are a step too far for many to want to participate. Given that at least one unit in Australia achieves a rate of neonatal encephalopathy of less than 1/3000 in monitored labours using the NICE assessment criteria, reasons to move to another technology would need to be compelling.

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Domperidone and breastmilk

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Is domperidone safe for lactating mothers and does it work as a galactagogue?

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It is a truth universally acknowledged that breastfeeding provides babies with the best start in life and is a major determinant of infant and

maternal health. In Australia, the National Health and Medical Research Council (NHMRC) recommends exclusive breastfeeding until six months of age, with the introduction of solid foods at around six months and continued breastfeeding until at least the age of 12 months. In 2010, the Australian National Infant Feeding Survey reported the encouraging statistic that 96 per cent of newborn babies were fully breastfed; however, by four months this figure had dropped to 39 per cent and by six months to only 15 per cent.¹

Around four to six weeks is a common time for mothers to have doubts about their milk supply, as many babies will experience fussy periods. The most widely reported reason for discontinuing breastfeeding is a perceived lack of supply.^{2,3}

Information and support

Before considering any pharmacological treatment, it is important to assess whether low supply actually exists in a particular breastfeeding woman. In reality, at least 95 per cent of mothers are able to produce sufficient milk for their babies without pharmacological or other intervention, especially when adequately supported and appropriately advised.³ Maternal medical reasons for low milk supply should be considered (such as primary mammary glandular insufficiency, hypothyroidism or polycystic ovarian syndrome) and women with little knowledge of the basics of breastfeeding should be given some education on how breastmilk is produced. Referral to a lactation consultant can clarify whether there is an actual or a perceived low supply. The website of the Australian Breastfeeding Association (ABA) has user-friendly information on increasing supply, and trained breastfeeding counsellors are available on the ABA national helpline. Frequent stimulation of the breast and complete milk removal at regular intervals coupled with emotional support and encouragement will help to ensure supply is promoted and maintained.

Galactagogues

Various pharmaceutical and herbal products have been tried by women in attempts to increase milk supply. The use of metoclopramide as a galactagogue was first reported 40 years ago⁴ and of domperidone more than 30 years ago.⁵ However, good evidence for the use of pharmaceutical galactagogues is still lacking.⁶ If a galactagogue is deemed appropriate to increase supply, the mother should be counselled that it will only be useful if frequent breastfeeding and breastfeeding support continues. Human lactogenesis is complex and, despite prolactin being required for lactation, there is no evidence that serum prolactin levels directly correlate with the volume of milk produced in lactating women.^{6,7}

Domperidone in lactation

Currently, domperidone is the preferred pharmaceutical galactagogue, owing to its favourable side effect profile (dry mouth and headache being the most commonly reported adverse effects). It passes poorly into breastmilk, with no adverse effects reported in breastfed babies. Domperidone is a dopamine antagonist with antiemetic properties. It is licensed in Australia for short-term (less than or equal to six months) treatment of symptoms associated with idiopathic diabetic gastroparesis and intractable nausea or vomiting from any cause. Its use as a galactagogue is off-label.

The Australian Medicines Handbook (AMH) states domperidone is 'safe to use' in lactation and 'does not readily cross the blood-brain barrier so extrapyramidal side effects are rare'. Conversely, it states that 'lactation stimulation is no longer listed as an accepted indication in AMH due to safety concerns and limited evidence of efficacy'. Instead, conservative, non-pharmacological measures for lactation stimulation are advised, such as 'breastfeeding more frequently and ensuring correct positioning and attachment'.

Very low levels of domperidone are detectable in milk as the molecule is poorly lipid soluble and highly protein bound in maternal plasma. It is also poorly orally bioavailable.⁷ Thus infants are expected to be exposed to less than 0.01 per cent of the maternal weight-adjusted dose. The American Academy of Paediatrics classifies domperidone as compatible with breastfeeding⁸ and Thomas Hale, a lactation expert and pharmacist, rates it an L1 (safest category) in his risk categorisation of medications in lactation L1-L5.⁹

Safety

Several warnings about domperidone have been issued by the US Food and Drug Administration (FDA)(2004), Health Canada (2012) and the European Medicines Agency (2014).¹⁰⁻¹² These warnings describe a small increased risk of serious cardiac side effects in patients over 60 years of age, those on long-term high-dose therapy (greater than 30mg/day for longer than a week) and those with pre-existing cardiac conditions, such as congestive heart failure. Prolongation of the QT interval, torsade de pointes, arrhythmias and sudden cardiac death have been reported. Often cited in the literature are reports of cardiac arrhythmia and sudden death in cancer patients treated with intravenous domperidone.¹³⁻¹⁶ Among these patients, the majority had co-morbid serious illnesses, were being treated with chemotherapy, and/or were severely hypokalaemic. Risk is greater in those taking other QT-prolonging medicines or CYP3A4 inhibitors concomitantly. Commonly prescribed examples include the azole antifungals (fluconazole, ketoconazole and itraconazole) and macrolide antibiotics (clarithromycin and erythromycin).

Breastfeeding mothers using domperidone do not, generally speaking, fall into the same demographics as the patients involved in the studies from which the warnings have been generated.¹⁷ Generally, breastfeeding women are young and healthy, but with the

average age of mothers increasing, prescribers are reminded that domperidone should be prescribed with caution and awareness of possible drug interactions.¹⁸

While intravenous domperidone has been withdrawn from the market worldwide, the FDA took the extreme step of removing ALL forms from the US market in 2004, and warned breastfeeding mothers specifically not to use it.¹⁰ Despite this, US mothers continue to be prescribed domperidone, obtaining it from compounding pharmacies and ordering online or from overseas. In September 2011, the FDA granted orphan drug status to domperidone specifically for 'treatment of hypoprolactinaemia in breastfeeding mothers'. This is only the first step in a long regulatory process that aims to eventually secure FDA approval.

Efficacy

It appears the real controversy lies not in the safety of domperidone in this population, but rather in its efficacy. Studies have tended to show a pattern of increased milk production, but they have generally been of poor quality; lacking randomisation, controls or blinding; comprising small sample sizes; recording high dropout rates and not optimising; or omitting non-pharmacological measures.²⁰

One well-designed study in mothers of babies less than 31 weeks gestation in a neonatal intensive care unit (NICU) found domperidone (10mg three times a day for two weeks) to be an effective galactagogue, increasing serum prolactin levels and breastmilk volume without altering milk composition.²¹ The majority of mothers initiated treatment within 21–28 days of delivery.

The ongoing EMPOWER study aims to evaluate the safety and efficacy of domperidone in mothers identified as having difficulty producing milk to meet the nutritional needs of their infant in the NICU setting. It is a multi-centre (Canada, Israel, Qatar and Chile), double-blinded, randomised controlled trial conducted over a two-week period.²² It also aims to determine optimal time to initiate therapy, dose and duration of treatment. Enrolment began in June 2012, with expected completion mid- to late-2015.

Summary

Overall, we conclude that although good-quality evidence is lacking for its use as a galactagogue, if domperidone is prescribed at recommended doses, for a defined time period, and only after non-pharmacological methods have failed, it is not expected to cause harm to mother or baby.

If a prescriber feels that a breastfeeding mother may benefit from use of domperidone as a galactagogue, the following recommendations should be followed:

- confirm a supply 'problem' really exists and trial non-pharmacologic lactation support before prescribing;
- screen for co-morbid medical conditions;
- discuss risks and benefits of the medication, and of breastfeeding itself;
- prescribe lowest effective dose and titrate up according to response;
- ensure regular follow-up to monitor for efficacy and side effects; and
- ensure the treatment is for a limited time only.

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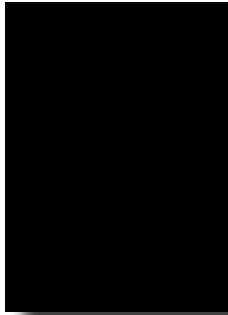
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To excise or ablate?

Should we excise or ablate all small deposits of endometriosis at laparoscopy?



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Endometriosis, characterised by the finding of endometrial-like tissue outside the uterus, is one of the most common gynaecological conditions associated with pain and subfertility among women of reproductive age.¹ It is one of the leading indications for laparoscopic surgeries both for diagnostic and therapeutic purposes in women presenting with pain or infertility.^{2,3}

Among the many on-going controversies regarding the management of this enigmatic condition is the question of whether it is worthwhile going to all the trouble of excising small deposits of endometriosis at laparoscopy, or whether cauterising them achieves the same outcomes in terms of pain and fertility (see Figure 1).

Within the limited scope of this article, we will attempt to address this fundamental question by reviewing current knowledge of the mechanisms of pain and infertility in association with endometriosis, considering the differences between excision and ablation in terms of diagnostic and therapeutic merits, and finally appraising the scientific evidence of excision versus ablation in terms of pain and fertility outcomes.

Pain symptoms most commonly associated with endometriosis are dysmenorrhoea, dyspareunia and non-menstrual pelvic pain.⁴ These symptoms may exist in variable combination and may fluctuate in severity from person to person and from time to time.⁵ There is good evidence linking pain to endometriosis, with estimated prevalence ranging

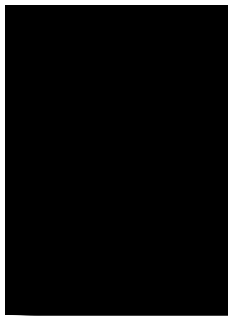
from 30–90 per cent among women undergoing laparoscopy for evaluation of chronic pelvic pain.⁶ There is also strong evidence supporting significant pain improvement and surgical treatment of endometriosis.^{7,8}

However, the relationship between pain and endometriosis is not clear cut as endometriotic lesions similar to those found in women presenting with pain have also been detected in up to 43 per cent of asymptomatic women.⁹ This observation suggests that the mechanisms by which endometriosis causes pain are still not fully understood and may vary from person to person.¹⁰ Pain from endometriosis is thought to arise predominantly through nociceptive, inflammatory and neuropathic pathways as a result of direct effects of cyclical active bleeding from endometriotic implants, and indirect effects involving the production of cytokines and nerve growth factors by endometriotic cells and activated macrophages activating silent nociceptors, irritating and stimulating neuronal ingrowth into nerve endings of pelvic floor nerves especially in the pouch of Douglas and the areas of the uterosacral ligaments.^{11–13} Another puzzling aspect between endometriosis and pain is the observation that the association between endometriosis stage and severity of pelvic symptoms is marginal and inconsistent.^{14–16} On the basis of these observations, one can appreciate the difficulty in evaluating pain as an outcome measure following surgical treatment of endometriosis.

How does endometriosis cause subfertility/infertility?

Similar to pain, there is considerable epidemiological evidence linking endometriosis and subfertility. These include higher prevalence of endometriosis from 25–40 per cent in subfertile women compared to 0.5 to five per cent in fertile women¹⁷, reduced fecundity from 0.02 to 0.10 in women with untreated endometriosis compared to 0.15 to 0.20 in normal couples^{18,19}, reduced fecundity after husband sperm insemination in women with minimal to mild endometriosis compared with those with a normal pelvis, reduced fecundity and cumulative pregnancy rate after donor sperm insemination in women with minimal-mild endometriosis compared with those with a normal pelvis²⁰, a negative correlation between the r-AFS stage of endometriosis and the monthly fecundity rate²¹, reduced implantation rate per embryo after IVF in women with moderate to severe endometriosis compared with women with a normal pelvis, an increased monthly fecundity rate and cumulative pregnancy rate after surgical removal of minimal to mild endometriosis.²² By contrast, others have found no difference in fertility outcome for women with infertility-related endometriosis compared to control and no clear association between the effect of different stages of endometriosis on IVF-ET outcomes.^{23,24}

While there is a strong association between endometriosis and infertility, no causal relationship has been clearly established. The many mechanisms by which endometriosis may cause subfertility include adhesions and distorted pelvic anatomy that prevent oocyte release or transport, increased peritoneal fluid concentration of inflammatory cytokines that may have adverse effects on



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oocyte function and quality, sperm motility, sperm DNA, sperm capacitation, oocyte-sperm interaction, fallopian function, impaired implantation and abnormalities in embryo quality.^{25,26} These conflicting observations highlight the difficulty when measuring fertility as an outcome following medical or surgical interventions, thus accounting for on-going lack of consensus about the choice and consequence of surgical treatment modality.

Factors that influence the choice of surgical method

In general, the aims of laparoscopic surgery of endometriosis are to remove (excise) or destroy (ablate) all visible endometriotic lesions, to divide adhesions and restore normal anatomy, and to repair damage to reproductive organs.²⁷ The choice of techniques for surgical treatment of endometriosis currently includes sharp dissection, electro-surgery, Argon Neutral Plasma Energy, laser or harmonic energy.²⁸

Ideally, the choice of surgical instrumentation (scissor dissection, electrosurgery, laser, harmonic, argon beam) and the mode of treatment surgical technique (excision or ablation) should be made on the basis of understanding of pathophysiology of the disease, the mechanisms of action, the tissue effects of the chosen surgical treatment modality and the outcomes of randomised controlled clinical trials.²⁹ However, most studies to date, including the few randomised controlled trials (RCTs) evaluating surgical treatment of endometriosis, have failed to give detailed technical description, standardised surgical technique or described the energy modality used. Nevertheless, major factors which should be considered in determining whether to excise or ablate include diagnostic benefit, tissue effects, haemostasis and time.

While laparoscopy is the recognised gold standard for diagnosis of endometriosis, in the absence of histological sampling, the false-positive rate with laparoscopic visualisation alone may approach 50 per cent, especially in women with minimal or mild endometriosis.³⁰ From this point of view, excision has a diagnostic advantage over ablation for histological confirmation.³¹ The question of whether selective excision of some lesions and ablation of the remaining would suffice both diagnostic and therapeutic outcomes (pain and fertility) has not been addressed.

Furthermore, the choice of instrumentation and the decision to excise or ablate should not only include consideration of speed, efficacy, safety and cost-efficiency, but also haemostasis, tissue tensile strength, extent of tissue injury, rapidity of wound healing (see Figure 2). With the exception of cold scissor excision, other devices (unipolar or bipolar electrosurgery, argon beam, laser, harmonic) all involve heat energy to denature protein, leading to vascular tamponade and haemostasis on the one hand, lateral thermal spread, delayed wound healing and risk of delayed damage to vital adjacent structures such as ureter, bowel, bladder on the other hand.³²

When taking the above factors into consideration, the overall theoretical and technical advantages which favour ablation over excision are speed, haemostasis, technical lenience, thus ease of adoption and generalisability, with perhaps equivalent safety but at the expense of incomplete destruction of deep endometriosis and lower diagnostic accuracy.³³

Appraisal of scientific evidence

In the recent Cochrane Review into laparoscopic surgery for endometriosis³⁴, the authors identified two RCTs that compared laparoscopic excision with ablation.^{35,36} Wright and colleagues

reported good symptom relief at six months irrespective of the treatment modality for the majority of participants in a study involving 24 women with mild endometriosis presenting with chronic pain.³⁵ While the authors gave details regarding the surgical technique, limitations from this study include inadequate sample size, the use of a ranked ordinal scale, the use of both coagulation and cut current in the excision group. Healey and colleagues also found no significant difference in pain outcomes between the two treatment modalities at 12 months.³⁶ However, at five-year follow-up, the same authors reported a significantly greater reduction in dyspareunia VAS scores in the excision group and a higher use of medical treatments among the ablation group.³⁷ The findings of this well-designed RCT have some limitations including a lack of detailed description of the surgical technique, failure to specify how the endometriotic lesions were excised or ablated and a high drop-out rate at five-year follow-up.³⁸

In terms of fertility outcome, meta-analysis of two RCTs in the 2010 Cochrane Review into laparoscopic surgery for subfertility associated with endometriosis concluded that laparoscopic treatment of minimal and mild endometriosis may improve the on-going pregnancy rate and live birth rate in couples with otherwise unexplained infertility.³⁴ In the Marcoux study, the laparoscopic treatment involved the destruction or removal of all visible endometriotic implants and the lysis of adhesions while the choice of instruments was left to the surgeons.³⁹ In the Group Italiano study that involved seven centres, the only description of the surgical intervention was that adhesiolysis was allowed in women allocated to resection or ablation of visible endometriosis with no details regarding whether all lesions were treated nor the choice of instruments.⁴⁰ To date, no RCTs have compared whether excision or ablation improves fertility in deep or stage 3 to 4 endometriosis.

Conclusions

The current level of understanding and evidence does not allow us to answer the question of whether we should excise or ablate all small deposits of endometriosis at laparoscopy in terms of pain and fertility. Nevertheless, there are several practical implications which can be drawn from the limited evidence. Firstly, the use of laparoscopic surgery (excision or ablation) has been shown to improve fertility in women with minimal or mild endometriosis, but evidence is lacking in women with more advanced endometriosis. Secondly, excision offers tissue for histological confirmation while visual inspection alone followed by ablation may be associated with a higher risk of false-positive diagnosis. Thirdly, ablation is quicker, easier, less vascular and technically less demanding than excision, but is not necessarily safer than excision. Finally, general consensus recommends excision over ablation for removal of deep endometriotic lesions.⁴¹

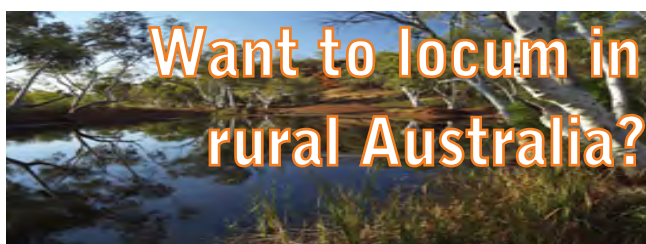
Figure 1. A large endometriotic implant being excised over the top of the left ureter.

Figure 2. Deep rectovaginal endometriotic nodule infiltrates through posterior fornix – being completely excised.

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After years of controversy, countless studies and statements from specialist societies, where are we now with mid-urethral slings?

Incontinence of urine affects one in three¹ Australians. The economic impact of incontinence in Australia in 12 months is \$42.9bn² (2010, adults over 15 years of age). Approximately 65 per cent of women with incontinence will have stress urinary incontinence (SUI). SUI is a highly prevalent condition of involuntary urine leakage when

the intra-abdominal pressure exceeds the urethral pressure typically associated with coughing, sneezing or exertion. SUI may impact significantly on quality of life, preventing many daily activities and limiting involvement in exercise and sport.

While SUI may occur in nulliparous women, it is more commonly associated with childbirth. The cause is presumed to be weakness in the pelvic floor structures, including disruption of the pubo-urethral ligaments and damage to connective tissue and muscles of the pelvic floor. The symptoms of SUI may, however, be caused by detrusor overactivity and intrinsic sphincter deficiency. This must be considered when planning treatment strategies as treatment needs to be based on correct diagnosis. It is not unusual to have a combination of problems leading to incontinence.

Commonly, intrinsic urethral sphincter deficiency (ISD) is included as SUI. ISD is defined urodynamically as a valsalva leak point pressure (VLPP) <60cm H₂O or a maximum urethral closure pressure (MUCP) <20cm H₂O.³ One may argue there is a significant difference between SUI owing to rotational descent of the urethra and/or pelvic floor dysfunction and symptoms of SUI owing to weakness of the urethral sphincter. ISD presents a particularly difficult group of patients who are at high risk of failure of current surgical techniques for SUI.

Diagnosis of SUI is by detailed history, examination, confirmation of complete bladder emptying and by exclusion of urinary tract infection and other lower urogenital tract pathology – commonly atrophic changes and coexistent prolapse. A urinary output chart is mandatory and provides much information. The recording of small frequent voids may indicate detrusor overactivity rather than uncomplicated SUI. Polyuria may indicate previously undiagnosed diabetes and this obviously needs exclusion. More commonly, bad habit with excessive fluid intake is the reason for the polyuria and before any decision on surgical management the urine output must be restored to normal (1.5L/24hrs).

Further investigation with urodynamic studies may be considered if there is any question about the diagnosis of uncomplicated SUI. It is interesting that there are very few situations where it is permissible to perform elective surgery without full and appropriate investigation.

Conservative management strategies should generally be considered before surgical intervention and may be instituted before urodynamic evaluation. These include: lifestyle changes; pelvic floor re-education; use of local oestrogens where appropriate; and weight loss in patients with a high BMI.

In spite of conservative management strategies, many women will require surgical intervention for more definitive control of the SUI. Since the mid-1990s, there have been significant changes in the surgical management of stress incontinence. The 'gold standard' colposuspension procedure, which had served well as a very successful operation for SUI, was challenged by the development of mid-urethral slings (MUS). These slings were readily adopted – being less invasive and associated with much faster recovery.

VOLUNTEER OBSTETRICIANS NEEDED IN ETHIOPIA

Up to one in 16 women are dying from pregnancy and related conditions during their lifetimes in sub-Saharan Africa. Almost all of these deaths can be prevented. Ethiopia accounts for more maternal deaths than any other country in the region.

Dr Andrew Browning, currently resident in Tanzania, is seeking volunteer qualified obstetricians and midwives to work in regional hospitals in Ethiopia.

One such hospital is in a town called Barhir Dar in Northern Ethiopia. It seeks to serve the millions of women who cannot afford basic maternity care in the government hospitals.

The volunteers will have the chance to impact on the lives of women and their families in a very real way and also to train the local health staff in emergency obstetric care.

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Fortunately, they have proven to have very satisfactory success rates both in the short and long term with minimal complications – fortunate because the rapid uptake of the use of MUS in general preceded adequate data and understanding of the ideal structure and weave of the tension-free vaginal tapes (TVT).

The answer to the question of how the MUS procedure works is not clear, but the presumption is that the sling corrects anatomic support of the urethra and may additionally provide a degree of compression to the urethra.

Recent controversies

Although the treatment of SUI with MUS has been universally adopted throughout the world, there have been attempts by certain legal firms to associate the use of MUS to the controversies related to the US FDA release in 2011 of a white paper⁴ expressing concern regarding the transvaginal placement of mesh for prolapse.

Various influential organisations, including RANZCOG and the Urogynaecological Society of Australasia (UGSA), the International Urogynecological Association (IUGA), the American Urogynecologic Society (AUGS) and the Society of Urodynamics, and the Society of Urodynamics Female Pelvic Medicine and Urogenital Reconstruction (SUFU), have released statements strongly supporting the current widespread use of MUS for stress incontinence.^{5,6}

There has been considerable evolution with MUS procedures during the last 15 years. Early multi-filament tapes were found to be associated with higher complication rates and discontinued in favour of uncoated, monofilament lightweight macroporous tapes.^{7,8} Initial MUS procedures involved a retropubic (RP) approach to sling placement. Subsequent development included transobturator (TO) placement of the tape and, more recently, the single-incision 'mini slings'.

Retropubic MUS

For many clinicians, RP MUS remains their preferred option. Credit



Figure 1. Failure to recognise RP tape traversing the bladder on the left side after perforated tape removed on the right (photo by Dr I Tucker).

for the introduction of MUS procedures is often given to Ulmsten and Petros. It may be argued that the original innovators were Raz and Stamey as it was their procedures that introduced the concept of mid-urethral surgical approach.

From the original 'bottom to top' approach of the TVT procedure developed the 'top down' Sparc procedure and there have been several 'clones' developed subsequently. The TVT and Sparc procedures, however, have the most data and are, arguably, the most studied of all gynaecological procedures. There have been some studies suggesting the TVT approach is superior to the Sparc, but the differences are less obvious in other studies, suggesting both procedures are successful and safe.^{9,10,11}

There is evidence that the RP approach may be indicated if the patient has coexistent ISD¹², but these data were obtained from earlier studies that also suggested more minimally invasive slings were less effective. More recent data dispute this and more studies are required.

RP MUS procedures have been extensively studied and long-term effectiveness of up to 80 per cent has been demonstrated in studies following the patients for up to 17 years.^{13,14}

RP slings are not without risk and entering the retropubic space can be hazardous. There is a significant risk of bladder perforation, a risk of bowel and intestinal perforation and a risk of haemorrhage and post-operative voiding difficulties. Owing to the risk of perforation of bladder and bowel, RP procedures should not be carried out if there has been a previous colposuspension or extensive retro-pubic surgery. Figure 1 shows a left sided bladder perforation present even though the surgeon had discovered and removed a right sided bladder perforation from the retropubic tape insertion.

As always, correct surgical technique is essential. The incidence of postoperative voiding dysfunction seems to be greater with RP MUS procedures, but it must be remembered that not all postoperative voiding difficulties are related to obstruction from the sling. Nevertheless, RP MUS remains popular and successful. As a result of the above possible complications, the TO approach to sling placement was developed.

TO MUS procedures

Insertion of the mid-urethral sling via the obturator foramen was introduced by Delorme in 2001.¹⁵ This 'inside-out' trans-obturator approach avoids the retro-pubic space thus reducing the incidence of bladder, bowel and intestinal perforation. Studies also suggest a reduced risk of postoperative voiding difficulties. There have been some criticisms regarding the lateral extent of placement of the tape and associated groin pain. de Leval et al¹⁶ introduced a more medial 'outside-in' approach. Both approaches are associated with very acceptable success rates between 77–91 per cent. There have been several 'clones' of the 'outside-in' approach.

Recent studies also suggest similar success rates for the TO MUS as for RP MUS¹⁷ and even question the previous suggestion that RP MUS procedures are the procedures of choice when there is coexistent ISD. There seems similar efficacy between the two well-studied procedures – Monarc and TVT-O.¹⁸ These TO MUS procedures, however, still require both vaginal and skin incisions.

Single-incision mini slings

In an attempt to further minimise the surgical approach to the treatment of SUI, The single-incision technique was developed. This

technique avoids any external skin incision and utilises a shorter length of tape.

Two approaches were initially developed: the TVT Secur and the MiniArc. The TVT Secur was abandoned owing to reported higher incidence of failure but the MiniArc/MiniArc Precise/MiniArc Pro MUS procedures remain in current use. These procedures are associated with less pain and haemorrhage.

Initial studies suggested success rates below that of other MUS procedures, but more recent studies following a slight modification of the technique have shown very acceptable success rates.^{19,20,21} Essentially, the tape is left a little more 'snug' around the urethra rather than in the 'tension free' RP MUS procedure.

With this procedure, there is very little chance of bladder perforation, minimal risk of haemorrhage and postoperative pain is minimal. It appears that the original criticism of the single-incision mini-slings is likely to have been premature and unjustified.

Treatment of ISD

Traditionally, peri-urethral bulking agents have been offered to patients with this very difficult problem. While failure rates remain significant, there is evidence that RP MUS procedures may be effective for ISD. This is confirmed with several studies including those by Schierlitz et al¹², Jeon et al²² and Araco et al²³ all showed significant success rates in this cohort. These studies also suggested that RP MUS was more successful than TO procedures when ISD was present. Other studies have produced contradictory results. Studies by Costantini E et al²⁴ failed to show any significant difference in outcome for ISD between RP MUS and TO procedures.

Treatment failures and complications

Current data suggest the failure rate for all MUS procedures is comparable. Failures are likely to occur because of:

1. inadequate surgical technique;
2. coexistent ISD;
3. coexistent detrusor overactivity;
4. occurrence of excessive exertion postoperatively and before adequate tissue ingrowth;
5. high BMI; and
6. other co-morbidities, such as excessive coughing, trauma and so forth.

Bladder perforation is largely a feature of RP MUS while groin pain is more commonly associated with TVT-O. Vaginal tape exposure is associated with all the procedures as is 'button-holing' of either anterior vaginal sulcus. Haemorrhage associated more with the RP MUS and occasional groin haemorrhage with TO MUS procedures.

Management of treatment failures

All patients with treatment failure require full assessment, including urodynamic evaluation and urethral pressure profilometry. The subsequent management will clearly depend on the results of the overall assessment.

Repeat surgery may confidently be offered to those patients with persistent SUI and this surgery may be a repeat of the previous operation or an alternative. A RP MUS procedure in the presence of sphincter deficiency may be a preferred option, although in those patients consideration may also be given to the injection of a peri/trans urethral bulking agent.

Tape exposures are usually relatively easily excised. Postoperative

voiding dysfunction is more problematic as the question of loosening or cutting the tape needs consideration if it is certain that the voiding difficulty is related to obstruction from the tape.

Discussion

The procedures that have been most studied include the RP TVT and Sparc MUS procedures, and more recent with less long-term data are the TVT-O and Monarc MUS procedures and the MiniArc Precise procedure. With the most recent data, all have very acceptable success rates. It may not be appropriate to apply these success rates to the 'clones'. The risk of tape exposure is present with all techniques but the incidence is low and acceptable. Pain is less with the more minimally invasive procedures as is postoperative voiding difficulty. Bladder/bowel perforation and significant haemorrhage are most likely to occur in the RP MUS procedures. All may be repeated should a failure occur.

Present data suggest that the three approaches are all satisfactory and may be considered as surgical options. The position statements by the various organisations representing urologists, urogynaecologists and gynaecologists have been authoritative, factual and totally supportive of the use of mid-urethral slings for the surgical management of stress urinary incontinence. These statements have emphasised that MUS procedures have been objectively studied more than any other gynaecological procedure and have undeniable success rates, very low complication rates and exceptional patient acceptance.

Conclusion

When the surgical option for stress incontinence is entertained, the choice of procedure will be up to the patient and the surgeon following full and complete explanation and confirmation that the condition of stress urinary incontinence exists. The surgeon may choose the procedure he/she is most experienced with and deems the most appropriate for the situation.

The importance of adequate training/mentoring/proctoring and credentialing is paramount to ensure that all surgeons are not only performing these surgeries at the highest standards, but are also performing surgery as the correct option for the correct reason. There is far more to operating than just the practical aspect. We are fortunate to have these very safe and successful MUS procedures allowing a well-tolerated and accepted, minimally invasive approach to the surgical management of stress urinary incontinence.

Conflict of interest statement

Dr Tucker has no conflicts of interest to declare. Current appointments include the following: Urogenital Prosthesis Clinical Advisory Group (UPCAG) of the Australian Federal Government Department of Health; National Vice President and Member of the Board of Directors of the Continence Foundation of Australia; Member of the Advisory Board of UGSA (Urogynaecological Society of Australasia); Member of the International Advisory Board of Acta Obstetrica et Gynecologica Scandinavica; Member International Advisory Board for Boston Scientific with Dr Peter Rosenblatt, Dr Karen Noblett and Dr Sandip Vasavada; Member of IUGA; Member of ICS; Member of the International Neuromodulation Society; and Secretary of the Audio-Engineering Society (Adelaide Section).

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Letters to the editor

Vaginal discharge

The article on chronic vaginal discharge (*O&G Magazine* Vol 16 No 3 Spring 2014 p47) gives an extensive list of possible infective causes, while under-reporting the non-infective causes. The cases discussed are not representative of the true case mix of aetiologies seen by gynaecologists and women's health GPs in urban Australia.¹ The medical literature on this topic is confusing, and the reader needs wide clinical experience in order to accurately interpret it.

We are concerned regarding the information offered on vaginal candidiasis. It describes only *acute* vaginal candidiasis, which is not a cause chronic vaginal discharge. There is no mention of recurrent and chronic vulvovaginal candidiasis.² These are common causes of chronic vaginal discharge and have specific diagnostic and therapeutic features.

The article asserts that the diagnosis of candidiasis 'is based on clinical symptoms', while describing examination and low-sensitivity microscopy. The statement 'primary culture is rarely indicated' suggests that the clinician does not need to perform a vaginal culture on the initial presentation. In Australia, any patient can obtain antifungal medication from a pharmacist without a diagnostic test and this frequently precedes a visit to a doctor. Once patients self-medicate, swabs become as insensitive as microscopy. A patient who has recurrent candidiasis with a negative swab as a result of treatment (a very common scenario) is difficult to differentiate from a patient with non-infective vaginitis. We therefore advocate vaginal culture at the earliest opportunity.

The very small section on non-infective discharge does not reflect the real world of office gynaecology in urban Australia. Space is given to cervical polyps, fistulae and malignancies, while neglecting to mention far less rare causes of abnormal discharge, such as desquamative inflammatory vaginitis³ and lichen planus.⁴ Vulval dermatoses, especially psoriasis, produce what may be mistaken for discharge because of weeping and desquamation from the skin surface. The author quotes a paper from Mumbai, describing increased vaginal discharge in the context of psychosocial distress. Psoriasis may flare with stress, but we have never been convinced that heavy discharge is caused directly by stress.

The most important omission however, is a discussion of the process of differentiating a normal from an abnormal vaginal discharge. Every women's health practitioner will be familiar with the (often young) woman who presents with the complaint of a chronic heavy discharge, but without other abnormal symptoms, and with an entirely normal examination and testing. The young woman is often distressed and keen for a 'solution', and the practitioner must therefore be very certain that she can tell normal from abnormal.

We hope these comments will lead to a better understanding of the topic.

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A/Prof Gayle Fischer
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Vulvovaginal disorders

Two articles on vulvovaginal disorders^{1,2} (*O&G Magazine* Vol 16 No 3 Spring 2014) describe some empirical treatment and suggest non-albicans yeasts need treatment when there is locally researched evidence to the contrary.³

An example of the potential for error managing vaginal yeast infection was a 32-year-old I saw this week with vulval psoriasis whose GP had made her condition considerably worse by prescribing boric acid pessaries for a non-albicans yeast found on culture. There is a relative lack of strategies in the articles for management of the particularly important condition of recurrent vaginal candidiasis. I am referring to overlooked treatments including depot medroxyprogesterone acetate (DMPA), my preferred treatment for the woman requiring contraception.⁴

When discussing vulval pain, it should not be forgotten that this is an eminently preventable condition, providing one avoids empirical treatment and attends to the inevitable sexual complications present in many of these women. Avoidance of empirical treatment means that the clinician needs to use a microscope⁴ and/or liaise with a pathology service when managing almost every patient with these complaints.

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Author's response

Dr Bradford, A/Prof Fischer and Dr Dennerstein make very good

points in their discussions around aspects of chronic vaginal discharge diagnosis and management. The first letter introduced some additional causes for non-infective chronic vaginal discharge, and also emphasised the importance of differentiating normal, as opposed to abnormal vaginal discharge. It is very pleasing that these learning points have been highlighted, they should certainly be considered in clinical practice. The second letter provides a useful clinical example highlighting the need to consider other treatments for recurrent vaginal candidiasis. This constructive feedback is very beneficial for directing further research on the topic and for providing a more complete picture on diagnosis and management.

Dr Patricia Car
MBBS, DRANZCOG

The proposed 2016 NCSP changes: the case for uncoupling the known from the unknown

The proposed changes to the cervical screening program in Australia as detailed in the article by Prof Ian Hammond (*O&G Magazine* Vol 16 No 3 Spring 2014 p26) makes interesting and informative reading. These changes consist of two broad elements:

1. discontinuation of screening for women under 25 years of age; and
2. the replacement of the two-yearly cervical smears with five-yearly HPV genotype (and cervical cytology where indicated) in women aged 25–74 years.

In the article, these two elements were coupled together as a single package, which is yet to be given approval by policy makers. It would appear, however, that these two elements though related, are separate matters and there might be some benefit in uncoupling and presenting them as two separate proposals to policy makers.

As pointed out in the article, there is overwhelming evidence for not screening women under 25 years of age and this has been the standard in many countries for years. This is because screening such women only inflicts unnecessary morbidity on them without any clinical benefit and at a huge cost. As an example, to see teenagers and women under 25 years of age who have undergone multiple loop excisions and even cone biopsy for CIN changes, as a result of the current screening program, is quite disheartening; even more so when these women are nulliparous.

There is no question in regards to the benefits of discontinuing screening for those under 25 years of age, but the same cannot yet be said for the other component of this proposal: five-yearly HPV genotype in women aged 25–74 years. As good as the evidence in support of this latter component might be, it remains in part an unknown quantity in regards to its real benefits and cost. This is because the potential benefits identified from it are mostly derived from clinical trials and it remains to be seen how things will play out when it is rolled out into the general population. There is also the possibility that some of the pitfalls associated with this component may turn out to be more than expected. For example, to state that it will lead to a 20 per cent increase in colposcopy referrals, but no increase in treatments may not materialise in clinical practice. Given the subjective nature of colposcopy, the likelihood is that more colposcopy will typically result in more cervical biopsy, which in turn will lead to more treatment (especially among those offering ablative treatment at the time of cervical biopsy) and this in turn would lead to further colposcopy and follow up appointments.

As the two proposals are currently being presented to policy makers as a single package, there is always the danger (albeit small) that rejection of one component implies rejection of all. This will then leave clinicians in a place where they will continue to subject younger women to unnecessary Pap smear, colposcopy and treatment.

It may therefore be beneficial to consider separating and presenting discontinuation of screening for the under 25 years as a separate entity, for earlier implementation, to policy makers. Given what is known about this, there is little to be gained by waiting till 2016 to implement this aspect of the proposal. It is inconceivable that policy makers will not immediately embrace such a proposal on the advice of experts in this field given the immediate cost savings and prevention of further unnecessary morbidity to such women.

Dr Benjamin A Onyeka
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Author's response

I thank Dr Onyeka for his comments and interest in the Renewal of the National Cervical Screening Program. I am pleased to note his support for the new age of commencement starting at 25 years. He has suggested that we might consider 'uncoupling' the other MSAC recommendations from the age of commencement, as in his opinion Primary HPV screening 'remains in part an unknown quantity'.

It is important to point out that the Renewal is a package and the objectives as documented in the MSAC report¹ and elsewhere² are listed below:

1. assess the evidence for screening tests and pathways, the screening interval, age range and commencement for both vaccinated and non-vaccinated women;
2. determine a cost-effective screening pathway and program model;
3. investigate options for improved national data collection systems and registry functions to enable policy, planning, service delivery and quality management; and
4. assess the feasibility and acceptability of the renewed program.

The MSAC recommendations primarily deal with points 1 and 2, but have included a recommendation for an invitation to screening.

Integral to the Renewal is the move from a Register 'reminder' system to an 'invitation and reminder' system, for both joining and exiting the program. Also of importance is the new later age for exiting the program. Enabling the registers to perform these expanded functions including receiving and storing data regarding HPV status, cytology, histology, colposcopy results and date of last contact, is a major process and a blueprint for these improved functions has been developed and is being considered by government committees. It is also hoped that the renewed Register will be national (virtual or real) and will allow for each woman to have one record, facilitating ease of access and data transfer across all jurisdictions for all concerned.

He would like us to move immediately to a delayed starting age of screening, but not move to HPV screening at the same time. Key to the policy decision is the operational aspect of the program including an upgraded and renewed register, not to mention the quality and safety monitoring and changes to workforce and

laboratory practice. The register is needed to invite women at 25 years of age before we can change the policy and this is not a quick or easy process.

In addition, there is overwhelming evidence supporting primary HPV screening and this in concert with the other aspects of the renewal will lead to at least 15 per cent fewer cases of cervical cancer and similar reduction in mortality. To delay introduction of this innovative strategy will lead to unnecessary morbidity and mortality. I note that the Netherlands is introducing a primary HPV screening program in 2016³, the NHS in England has six pilot sites assessing primary HPV testing⁴ and that in Australia the Compass trial⁵ has commenced and this will further inform the Renewal.

He has also raised concerns regarding the projected increase in colposcopy and feels that increase in treatment is inevitable. He has stated that an increase in cervical biopsy is likely and that this will in turn lead to more treatment 'especially among those offering ablative treatment at the time of cervical biopsy'. I would point out that our current NHMRC guidelines⁶ state that ablative treatment should not be carried out in the absence of histologic diagnosis and treatment of low-grade lesions is specifically not recommended and high-grade lesions should only be treated (ablative or excisional) when a histologic diagnosis is available.⁶ Furthermore, it is anticipated that the projected increase in colposcopy will be transient as the impact of HPV vaccination continues to reduce the at risk population.

Finally, I note that the Australian Health Ministers Advisory Council met on the 19 September and has approved the MSAC recommendations and endorsed the Interim Implementation Plan for the Renewal.

Prof Ian Hammond

Chair, Steering Committee for the Renewal Implementation Project
National Cervical Screening Program

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Case reports

Laparoscopic management of tubo-ovarian torsion and necrosis secondary to dermoid cyst in early pregnancy

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Background

Adnexal torsion is a rare cause of acute abdominal pain and diagnosis can be challenging because the presentation is often characterised by non-specific symptoms. It requires a high clinical suspicion for prompt diagnosis in order to save the adnexal organs.

Case report

A 32-year-old primiparous woman presented at 17 weeks with sudden onset of right iliac fossa pain that woke her from sleep. She described the pain as severe and constant, sharp in character, radiating down to her right groin and associated with nausea and vomiting. The patient did not have any vaginal discharge, bleeding or contractions. There was no other medical, surgical or gynaecological history of note. The pregnancy was naturally conceived with a normal antenatal course. Imaging to date had been unremarkable.

On examination, the patient was distressed, but afebrile and haemodynamically stable. She had right lower quadrant tenderness, with a palpable mass. Pelvic ultrasound reported right adnexal 75x42x34mm ovoid heterogeneous mass with no internal vascularity that appeared to be separate from the uterus. Blood flow to the right ovary could not be demonstrated. The fetal examination was normal.

Acute appendicitis was a differential diagnosis, but seemed unlikely. Adnexal torsion, although considered, was not convincing. The patient was admitted for analgesia and observation. On the following day, her abdominal pain remained localised in the right iliac fossa and seemed to improve. Bedside ultrasound was performed by the obstetrics and gynaecology team and suggested a dermoid cyst. With adequate analgesia, the patient remained comfortable and the inflammatory markers remained normal.



Figure 1. Transabdominal pelvic ultrasound: right heterogeneous mass with no vascularity on colour Doppler. No evidence of calcification, fat-fluid level, or necrosis and with a texture of haemorrhage. No free fluid. Ovary could not be separately identified from the mass. Courtesy of Gosford Hospital Radiology Department and Dr Rajiv Rattan.

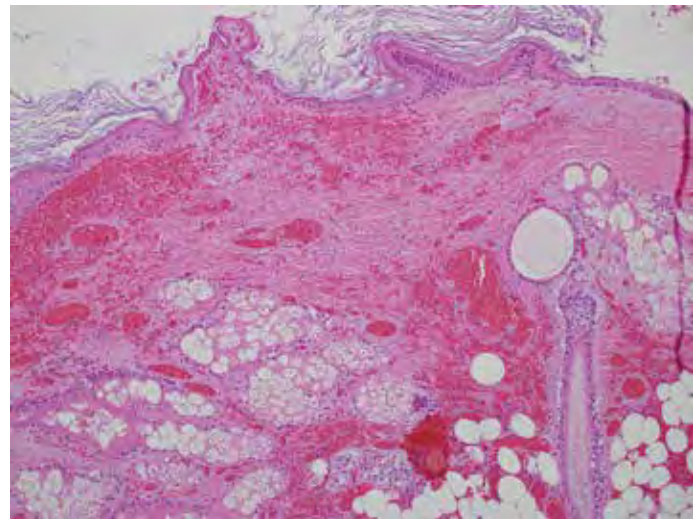


Figure 2. Histology slide. Torsed dermoid cyst showing haemorrhage and necrosis, squamous epithelium, sebaceous glands, adipose tissue, hair shaft and area of layers of keratin. [H&E stain]. Image courtesy of Gosford Hospital Pathology and Dr Julienne Grace.

On the third day, her pain worsened with analgesia providing little relief. By this time, significant tenderness in the right iliac fossa with guarding was found. The C-reactive protein became elevated to 76mg/L. A decision was made for laparoscopy that revealed a 15cm necrotic tubo-ovarian mass with fallopian tube torsion. Detorsion did not return normal colour to the ovary or fallopian tube, so right salpingo-oophorectomy was performed. There were no postoperative complications or signs of preterm labour. Histology revealed tubo-ovarian torsion secondary to a benign dermoid cyst.

Pre-operative serum tumour markers CA 19-9 and CA 125 returned elevated readings at 497.4 and 70.5, respectively. Of note, spontaneous labour occurred at 40+8 weeks gestation and delivery was by caesarean section for prolonged second stage.

Discussion

Adnexal torsion accounts for about three per cent of gynaecological emergencies and is usually caused by the total or partial rotation of the ovary and the fallopian tube on its vascular pedicle.³ It can occur in all ages, but is more common during the reproductive years⁴ because of the development of a corpus luteal cyst during the

Key points

- Adnexal torsion should be considered in any presentation of sudden-onset lower abdominal pain and adnexal mass.⁶
- Diagnosis can be challenging, owing to the relatively non-specific symptoms and laboratory findings.⁶
- Imaging modalities may be suggestive, but are not conclusive.
- Prompt diagnosis and management is essential to optimise outcomes.

menstrual cycle.³ It is a rare cause of abdominal pain in pregnancy, with an incidence of five per 10 000 pregnancies.⁵

Factors that predispose to adnexal torsion include tubal congenital or acquired anomalies, such as hydrosalpinx and tubo-ovarian masses.⁶ It may be associated with stimulation during fertility treatment, most notably IVF.⁵ An average 50–80 per cent of cases are associated with an ovarian tumour, typically benign, or with a large heavy cyst.³ When it occurs during pregnancy, torsion is common in the second and early third trimester and necrosis may precipitate peritonitis with preterm labour.^{2,5,6} The commonest presenting symptom is lower quadrant pain, with non-specific symptoms such as nausea, vomiting and fever. The pain is typically sudden in onset and may be constant or paroxysmal, radiating to the thigh or groin.⁶ Torsion is more common on the right side, presumably owing to the sigmoid colon, which makes adnexal movement less likely on the left.⁴

No specific laboratory tests are helpful in the evaluation of a patient for suspected adnexal torsion in pregnancy.³ A raised white cell count is a non-specific finding and unreliable indicator of torsion. Imaging usually reveals an enlarged displaced ovary or adnexal mass, sometimes with evidence of haemorrhage and free fluid.³ Doppler flow studies are commonly equivocal³ and the absence of adnexal blood flow has a poor negative predictive value.²

Management of adnexal torsion in pregnancy is controversial owing to the associated risks.⁵ Laparoscopy during pregnancy has an increased risk of injury to the uterus and possibly pregnancy loss.⁸ The safest time to perform laparoscopic surgery in pregnancy is usually the second trimester, and surgery prior to the third trimester has the least risk of premature delivery.⁹ However, it remains unclear whether preterm labour associated with laparoscopic surgery in pregnancy is secondary to the underlying pathology or surgery itself.⁹

Acknowledgements

Thank you to Dr Julienne Grace who provided the histological examination of the lesion and Dr Rajiv Rattan who provided the pelvic ultrasound examination.

Consent

Written informed consent to publish this case report and images was obtained from the patient.

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Eclamptic seizure when on a magnesium sulphate infusion

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Case report

A nulliparous 25-year-old patient presented to Nelson Maternity Unit at 34 weeks gestation. She had seen her midwife two hours earlier because of feeling unwell with a frontal headache for the previous few days, and loose bowels for one week. She had less than usual fetal movements. On the day of admission she had also experienced constant, quite severe epigastric pain. Her midwife had recorded a BP180/120 and urine dipstick of 3+ protein.

The patient had a normal pregnancy to date, no relevant medical

problems, though the patient's mother had pre-eclampsia in both her pregnancies leading to two preterm deliveries.

On arrival at Nelson Hospital, at 3pm, blood pressure (BP) was 180/130 with 3+ protein on urine dipstick. On examination she looked uncomfortable with a tender epigastrium, soft non-tender uterus appropriate for dates, fetal head 5/5 palpable abdominally, brisk reflexes and five beats clonus bilaterally. Vaginal examination showed: cervix 3cm long, closed, posterior, head at station -3, CTG reactive.

Bloods: Hb 153, Hct 0.46 Pt 173, Cr 89, ALT 135, urate 0.52, in other words, haemoconcentrated, mildly abnormal renal and liver function with normal coagulation profile.

Magnesium sulphate infusion was commenced at 3.15pm using 5g in 100ml over 20 minutes loading dose then maintenance rate of 15ml per hour, in other words, 1.5g per hour.

At 3.25pm, labetalol 200mg was given orally, at 4.45pm her blood pressure was still 184/132 so nifedipine 10mg oral stat was given, BP gradually decreased to 154/106. Betamethasone 11.4mg im was given at 6.30pm.

At 6.30pm her blood pressure was 156/108 with very concentrated urine (very abnormal brown sludgy urine) her headache was easing, reflexes 2+, JVP +2.

The patient consented to a caesarean section and the anaesthetist recommended one litre of Hartmann's solution one hour pre-operation. Because of the imminent spinal/epidural, no further anti-hypertensive was given.

Under a combined spinal epidural a growth-retarded female infant was delivered by routine caesarean section at 8.03pm. Apgar scores were 7, 9 and 10, birth weight 1.695kg and the neonate was admitted to NICU in good condition; the estimated blood loss was 300ml.

While I was closing the second layer of uterus, the patient had a tonic-clonic seizure lasting two minutes, the anaesthetist maintained her airway and administered propofol 20mg, a second bolus of 5g magnesium sulphate was given by the paediatrician under my instructions after a midwife collected it from the eclampsia pack on delivery. An arterial line was placed by the anaesthetist, intrathecal morphine administered pre-removal of epidural and the patient transferred to ICU.

In ICU, intravenous infusion magnesium sulphate 2g per hour was commenced, reflexes were present at every 15-minute check. Methyldopa 250mg orally every eight hours was commenced, as this is believed to be neuro protective. Charted hydralazine if blood pressure >155 systolic or >100 diastolic. Bloods at midnight: Pt 55, APTT 36, magnesium 3.1 (1.6-3.3mmol/l therapeutic), ALT204, Cr111 - clexane withheld, note the significant deterioration in coagulation markers, renal and liver function.

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Day one post caesarean: normal lochia, the patient reported no headache/epigastric pain and feeling much better. Blood pressure was controlled on methyldopa and two doses iv hydralazine overnight, three beats clonus bilaterally, fluids restricted to 1.5 litres per 24 hours, urine output >20ml per hour and paler colour than pre-caesarean. Her blood tests in the morning were: Hb 111, Pt 47, APPT 32, INR 1.1, ALT 166, Cr104. Evening bloods: Hb94 magnesium 3 (mid target range).

Day two post caesarean: no hydralazine needed, 154/70 maximum blood pressure, feeling well. Hb83, Pt65 normal coagulation profile otherwise, good diuresis, magnesium infusion decreased to 1g per hour and three hours later stopped. In the evening, reflexes were hyperactive and six beats clonus so magnesium restarted at 1mg per hour.

Day three post caesarean: magnesium infusion stopped at 1pm. Blood pressure stable on methyldopa, mobilising Hb75, Pt88 reflexes normal, but clonus four beats persisted.

Day four post caesarean: transferred to ward thanks to steady progress. There was marked bruising around wound. Clexane was started when platelets normalised. Hb normalised without blood transfusion, suggesting the anaemia was reflecting fluid shifts not blood loss. Her subsequent recovery was straightforward.

Discussion

Magnesium sulphate is used to prevent or stop an eclamptic convulsion, to prevent immediate recurrence of convulsions and to gain time for antihypertensives to function. Magnesium sulphate prevents or controls convulsions by blocking neuromuscular transmission. It decreases the amount of acetylcholine secreted at the end plate by the motor nerve impulse.¹ It also causes vasodilation of cerebral vasculature reversing the cerebral ischaemia thought to trigger eclampsia. Magnesium should be used with caution in women with impaired renal function because of the risk of magnesium toxicity and is contra-indicated in patients with heart block or myocardial damage.

Data from the Collaborative Eclampsia Trial² provided strong evidence that magnesium sulphate is the drug of choice for women with eclampsia. Most Australasian units use intravenous regimes as they are less painful than intramuscular injections. The intravenous regimen used in the trial was 1g per hour with a 4g loading dose, and monitoring was clinical rather than by serum concentrations of magnesium. At 1g per hour, clinical monitoring of reflexes and respiratory rate appeared to be safe without the need to check serum magnesium levels. 1g per hour, 1.5g per hour and 2g per hour are all commonly used regimes. Dose is adjusted according to patient response, clinical signs of toxicity and serum magnesium levels (aim to achieve levels of approximately 1.6–3.3mmol/L).

In this case the 2g per hour magnesium infusion led to levels of 2.8–3.1mmol/L, which is what we wanted in the higher half of the target range as the patient had proven lower levels were not sufficient to prevent her convulsions. Her reflexes were never absent and respiratory rate never low. It would be more usual to give a smaller second loading dose of 2–4g but here the infusion was delayed while the patient was transferred to ICU.

A hypertensive emergency is defined as an acute-onset, persistent (lasting 15 minutes or more), severe systolic (greater than or equal to 160mm Hg) or severe diastolic hypertension (greater than or equal to 110mm Hg) or both in pregnant or postpartum women with pre-eclampsia or eclampsia.³

In a recent case series of 28 women with severe pre-eclampsia and

stroke, all but one woman had severe systolic hypertension (greater than or equal to 160mm Hg) just before a haemorrhagic stroke, and 54 per cent died, whereas only 13 per cent had severe diastolic hypertension (greater than or equal to 110mm Hg) in the hours preceding stroke.⁴ A similar relationship between severe systolic hypertension and risk of hemorrhagic stroke has been observed in non-pregnant adults.⁵

Intravenous or oral labetalol, intravenous hydralazine and oral nifedipine have all been used to control severe hypertension in pregnant women. Aiming for a systolic blood pressure of less than 150 and diastolic less than 100mmHg is generally recommended.⁶

In our case, I think that starting with intravenous hydralazine or labetalol would have brought down the patient's blood pressure faster. Starting the magnesium loading dose was prioritised over administering an intravenous anti-hypertensive. While oral anti-hypertensives are appropriate until an intravenous line is sited I believe once a line is sited intravenous anti-hypertensives should be the top priority.

Conclusion

I have presented an unusual case where our first line 1.5g per hour infusion of magnesium sulphate did not prevent an eclamptic convulsion. I have also emphasised the importance of treating blood pressure first in a hypertensive emergency.

Consent

Written informed consent to publish this case report and images was obtained from 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.

Paracetamol in pregnancy

Paracetamol is one of the drugs most commonly used by pregnant women and is listed as category A by the Australian Drug Evaluation Committee. Paracetamol has been used for many years during pregnancy and is generally thought to be very safe.

Thompson et al report on 871 children in the Auckland Birthweight Collaborative Study.¹ Initially enrolled at birth between 1995 and 1997, the study reports the results of child behaviour by parent report at age seven and by parent and child reports at age 11. Reports were standardised using the Strengths and Difficulties Questionnaire (SDQ). Use of analgesics, including paracetamol, was ascertained by interviews conducted soon after the study enrolment, following birth of the child. Paracetamol was by far the most common analgesic used by the mothers during pregnancy, with 49 per cent of women reporting use compared with 5.3 per cent using aspirin and 1.3 per cent using other anti-inflammatories.

The results show that there were significantly higher scores on the SDQ in children of mothers who had taken paracetamol during pregnancy, compared to those who had not, at both seven and 11 years of age. The authors conclude that paracetamol use during pregnancy is associated with a higher risk of attention deficit hyperactivity disorder later in childhood. There was not a similar association with the other analgesics or antibiotics included in the study. If this result is replicated in larger long-term studies it will of interest to many pregnant women.

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Term breech delivery

Since the Term Breech Trial there has been an increase in the overall caesarean rate for breech presentations. Sullivan et al report that, in 2005, the elective caesarean rate for breech presentation in Australia was 77 per cent, with an overall caesarean rate of 96 per cent.¹ One consequence of this is that current data regarding the safety of vaginal breech birth has become scant. In the Netherlands, however, the elective breech caesarean rate is 60 per cent with a total caesarean rate for breech delivery of 80 per cent. This paper analyses neonatal outcomes for breech deliveries following the publication of the Term Breech Trial, in 2000, with particular emphasis on the outcomes of the 40 per cent of women selected for planned vaginal delivery.² The authors analysed 1.4 million term deliveries from the Netherlands Perinatal Registry 1999–2007, of which more than 58 000 were breech. The selection of these years allowed them to analyse changes in breech delivery before and after the Term Breech Trial: the elective caesarean rate increased from 24 per cent before to 60 per cent afterwards. There was an accompanying reduction in the overall perinatal mortality rate from 1.3 per cent to 0.7 per cent (OR 0.51; 95 per cent CI 0.28–0.93), with a larger effect in nulliparous compared with multiparous women. There were also reductions in low Apgar score and neonatal trauma. In women having a planned vaginal delivery, there was no decrease in perinatal mortality after November 2000 (1.7 per cent versus 1.6 per cent; OR 0.96; 95 per cent CI 0.52–1.76). The authors calculated a number needed to treat of 338 elective caesareans to prevent one perinatal death. Interestingly, the authors report a range of planned breech caesarean rates in different institutions from 14–80 per cent. They attempted to identify subgroups of women in which planned vaginal delivery would be safe, but were unable to do so from the data, suggesting elective caesarean section would be the safer option for most women with a breech presentation at term.

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Long-acting contraception and teenage pregnancy

The teenage pregnancy rate in Australia is about 15 births per 1000 girls aged 15–19 while it is about 26 per 1000 in New Zealand.¹ Teenage pregnancy is associated with social and financial costs including decreased educational attainment and welfare dependence. Long-acting reversible contraceptives (LARCs) including implants and intrauterine devices (IUDs) have been associated with decreased rates of teenage pregnancy, but fewer than five per cent of US teens report using them despite them being acceptable to them. A new study reports on an innovative program in which women are provided standardised information regarding reversible contraceptives, with an emphasis on LARCs, and provided with the contraceptive of their choice at no cost.² The Contraceptive CHOICE program targeted unplanned pregnancy in girls and women aged from 14 to 45 years of age, although this paper reports on data from 1404 teenage girls. After the education and counselling part of the project, 35 per cent of girls chose an etonogestrel implant, 32 per cent chose a hormonal IUD, five per cent chose a non-hormonal IUD while 13 per cent chose the oral contraceptive pill and five per cent chose a contraceptive ring. Prior to enrolment in the project, 97 per cent of participants were sexually experienced, 47 per cent had had an unintended pregnancy, 18 per cent had had an abortion and 24 per cent had had a diagnosis of a sexually transmitted disease. At one, two and three years 92 per cent, 82 per cent and 75 per cent of participants were available for follow up. During the follow-up period, participants in the CHOICE project had much lower rates of pregnancy, births and abortion compared to sexually experienced teenagers (34/1000 versus 159/1000, 19/1000 versus 94/1000 and 10/1000 versus 42/1000, respectively). This article shows that the rates of teenage pregnancy may be substantially reduced by provision of no-cost long-acting contraception.

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- 2 Secura GM, Madden T, McNicholas C, et al. 2014. Provision of no cost, long-acting contraception and teenage pregnancy. *N Engl J Med*, 371: 1316-1323.

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 *'A 50-year-old para 2 has been using transdermal oestrogen with Mirena IUCD providing endometrial protection since the onset of premature menopause ten years ago. She tried stopping it a year ago, but had a resurgence of vasomotor symptoms. She would like to continue HRT for as long as possible. Apart from a BMI of 28, she has no medical or family history of note. She has not had a mammogram for more than five years as she has made a fully informed decision to avoid mammography, believing its risks outweigh the benefits. Given the early onset of menopause, what advice should I give her about when to discontinue HRT? Should we continue prescribing HRT to a patient who declines breast screening?'*

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a

Physicians who look after menopausal women are usually very concerned about weighing up the long-term risks and benefits of HRT. In contrast, those who suffer significant hot

flushes mostly want their symptoms treated so they function and can sleep at night. In the 1990s HRT was hailed as a treatment that most, perhaps even all, postmenopausal women should take for many years. Then, after the dramatic release of the breast cancer data from the Women's Health Initiative (WHI) on 10 July 2002, the pendulum swung in the opposite direction. Fear to prescribe HRT gripped many doctors and some women with severe menopausal symptoms suffered.

A significant minority of women will have severe menopausal symptoms for many years (some forever) and so, for these women, the clinical decision usually comes down to what is the safest way of giving HRT long term. There have been some key studies and a number of excellent reviews of the risks and benefits of long-term HRT.¹⁻⁶ A short summary of the findings of these reviews follows.

For many healthy women, most types of HRT (oral, transdermal, tibolone) are safe up to the age of 60 years. In the WHI cohort, those who were under 60 years of age and on oral HRT (Premarin-Provera) had a significantly lower risk of death than the control group. Those over 60 years of age on oral HRT had a similar risk of death to the control group. From a woman's perspective, most of the concern about using HRT is focused on breast cancer risk. In WHI, the group on combined oral HRT had an increased risk of eight per 10 000 women per year after five years of usage. This was statistically significant using uncorrected data, but not when

corrected for multiple comparisons. Also, in the same cohort, there were eight fewer other cancers per 10 000 women per year.

We will shortly examine the breast cancer issue in more detail, but it is also important to point out that for those women who 'flush forever', the main risk of long-term HRT as they move beyond 60 years of age is actually venous (DVT, pulmonary embolism) and arterial thrombosis (stroke and other atherosclerotic disease). In this respect, transdermal oestrogens (patches, gels, creams, implants) are safer than orals because they avoid hepatic first-pass. In one major review⁵ there was no excess of thrombosis with oestrogen patches. In contrast, in WHI, there was a steady increased risk of embolism with age for those on oral HRT.

Returning to the breast cancer issue, it is important to consider all the patient's risk factors. There are convenient Australian (www.seemyrisk.com/) and US breast cancer risk calculators available (www.cancer.gov/bcrisktool/). Relevant to our patient, menopause under the age of 45 years reduces breast cancer risk in later life (as does delivering your first baby under the age of 25 years). It can be very helpful to calculate a patient's breast cancer risk over the next ten years; on and off HRT. Patients are often surprised how small an effect HRT has on their breast cancer risk.

One interesting finding from WHI was that those subjects on unopposed oestrogen (hysterectomised subjects) had a significantly lower risk of developing breast cancer. It is beyond the scope of this short article to outline the likely explanations, but it has focused a lot of breast basic research on the progestin rather than oestrogen. It has also piqued interest in novel delivery systems for progestins/progesterone to selectively protect the endometrium from the well-known stimulatory effects of oestrogen and minimise the systemic exposure of the body to progestins. Our patient has a Mirena device in place that will very effectively protect her endometrium, while her systemic exposure to the synthetic progestin will be minimal.

Another interesting approach from Europe has been the suggestion to use twice weekly progesterone pessaries. In one small study,

subjects were using oestradiol patches changed twice weekly and on the day they changed the patch, they inserted a 100mg progesterone pessary high in the vagina.⁷ This approach offered endometrial protection with barely detectable progesterone levels in blood.⁷ Crinone gel four per cent (45mg progesterone) twice weekly has also been used in this way.⁸ There is an abundant literature dating back to the 1990s describing the direct delivery of drugs from the upper vagina to the uterus. Both Crinone (eight per cent) and progesterone suppositories (100mg) are available in Australia and New Zealand (PBS approved for IVF).

Finally, I shall discuss the issue of screening mammography raised by our patient. Unknown to most Australians, there has been a huge (and at times, heated) debate in Europe (especially in the *British Medical Journal*) about the benefits and risks of screening mammography.⁹⁻¹² It came to a head when a Danish group showed that for the first time in 20 years, screening mammography no longer impacted breast cancer death rate in that country.⁹ This study and others⁹⁻¹³ have two major explanations for this surprise finding.

First is that breast cancer treatments have steadily improved over the last 20 years. In most Western countries the death rate from breast cancer has been falling. In Australia, between 1994 and 2011, the age-standardised mortality rate for breast cancer in women decreased by 30 per cent (from 30.9 deaths per 100 000 women in 1994 to 21.9 deaths per 100 000 women in 2011. See <http://canceraustralia.gov.au/affected-cancer/cancer-types/breast-cancer/breast-cancer-statistics>).

Second is the problem of over-diagnosis. In 1997, Welch and Black¹³ reviewed autopsy studies and found 1.3 per cent had invasive breast cancer and nine per cent had breast DCIS. Most

of these lesions were too small to be detected by mammography. However, it seems clear that many of these small tumours never progress and some may even regress spontaneously. More recently, Prof Welch has nicely summarised the problem¹⁰ – ‘over-diagnosis refers to the detection of abnormalities that will never cause symptoms or death during a patient’s lifetime. Over-diagnosis of cancer occurs when the cancer grows so slowly that a patient dies of other causes before it produces symptoms or when the cancer remains dormant (or regresses). Because doctors don’t know which patients are over-diagnosed, we tend to treat them all. Over-diagnosis therefore results in unnecessary treatment.’

It is interesting to note that to date there has been no public discussion of this controversial subject in Australia.

Our patient is using oestrogen patches and has a Mirena device fitted. She is using arguably our safest HRT system. Assuming she has been informed about the risks and benefits of her HRT, it would seem reasonable for her to continue on HRT for another five-to-ten years, if she wishes and then to try to wean off the patches during the cooler months. If severe symptoms keep returning, she may be in that significant minority of women (around 10–15 per cent) who have severe flushes forever. Non-oestrogen treatments such as clonidine, selective serotonin reuptake inhibitors and gabapentin could be discussed (these have their side effects too, of course). I suspect our patient has discovered the European controversy about the risks and benefits of screening mammography and I don’t see how that changes her HRT decision at all.

Thus, I would support her decision to continue on HRT for the moment and not have mammographic screening.

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Minding the gap

Dr Marilyn Clarke
FRANZCOG
Chair, Reconciliation Action
Plan Working Party
Member, Indigenous
Women's Health Committee

RANZCOG is committed to improving the health and wellbeing of Indigenous women of Australia and New Zealand and their families. The College is active in this endeavour and thanks are owed to the members of the Indigenous Women's Health Committee for their dedication.

On 2–4 May, RANZCOG held its third triennial Indigenous Women's Health Meeting, in Adelaide. The inaugural meeting was held in Darwin, in 2008, and the second in Cairns, in 2011. This meeting attracts an eclectic mix of delegates, including Fellows, GPs, midwives, Aboriginal Health Workers and researchers. It is a palpable demonstration of collaboration between multiple disciplines to learn, share and ultimately improve what we can in our spheres of influence for the betterment of Indigenous women's health – exemplified by the meeting's theme 'Sharing knowledge, creating change'. The meeting this year expanded the content on Maori women's health and also, for the first time, had a session focusing on Pacific Islander women's health.

RANZCOG President Prof Michael Permezel and CEO Mr James McAdam attended proceedings, demonstrating the College's commitment to contributing to Indigenous women's health. Sincere gratitude was expressed to the organising committee members, led by Dr Jacqueline Boyle, for their hard work in putting together an informative and productive meeting. Webcasts of presentations from this meeting can be viewed on the RANZCOG website.

Reconciliation Action Plan

An important and significant achievement for the College has been the development of a Reconciliation Action Plan (RAP). Reconciliation Australia (RA) is a not-for-profit organisation established to promote the reconciliation between Australia's Indigenous and non-Indigenous peoples. It has numerous programs and resources, with RAPs being an example of one such resource. Under the auspices of RA, organisations are encouraged to develop RAPs, with the idea of putting practical steps into place to achieve goals that will contribute to reconciliation. A College working party was established to work on the project, and this culminated in the official launch of the RANZCOG RAP at the IWH meeting in Adelaide. The RAP lays out a plan for deliverable actions, with a timeline and responsible person to help achieve these goals. The plan will be reported on annually and revised to continually assess its progress and how we can build on achievements. The important principle is that it demonstrates the College's commitment to practical ways in which it can contribute to Aboriginal and Torres Strait Islander women's health, and that changes can be modest to begin with and be built upon. The RANZCOG RAP can be accessed via the College website or through www.reconciliation.org.au.

Australian Indigenous Doctors' Association

One of the RAP's goals is to further develop a working relationship with the Australian Indigenous Doctors' Association (AIDA). AIDA is a not-for-profit non-government organisation that provides support for Aboriginal and Torres Strait Islander doctors and medical students, and provides advocacy and leadership in the

national sphere in Indigenous health issues. Currently, there are approximately 204 Aboriginal and Torres Strait Islander doctors in Australia (for population parity, there should be over 2000 Indigenous doctors). There is obvious potential for synergy between our organisations in this space. RANZCOG is proud to have four current Aboriginal or Torres Strait Islander Trainees in the Fellowship program, with a fifth to start next year. This is the biggest cohort of Indigenous Trainees in a medical college, after the RACGP. RANZCOG attended AIDA's recent annual



Prof Michael Permezel, RANZCOG President, delivers the keynote speech at the 2014 Indigenous Women's Health Meeting, which was held in Adelaide.



This painting, titled 'Reconciliation', is by the award-winning artist Samantha Snow and was commissioned for RANZCOG's RAP document. It now forms part of the College Collection at College House, Melbourne.

conference, with both a sponsored booth and participation in a workshop, to encourage Aboriginal and Torres Strait Islander medical students and doctors into Fellowship training programs. It is important for the College to not only attract Indigenous doctors into our speciality, but also provide support and mentoring to ensure they get through to Fellowship.

CPMC Indigenous Health Subcommittee

RANZCOG is also represented on the Committee of Presidents of Medical Colleges (CPMC) Indigenous Health Subcommittee, along with all the other medical colleges, AIDA and National Aboriginal Community Controlled Health Organisation (NACCHO). One project of several this subcommittee has been working on is the development of a core curriculum on Aboriginal and Torres Strait Islander health. Medical schools have come a long way in improving the Indigenous health component of their curriculum and the specialist colleges need to continue that momentum by vertically integrating the Indigenous health component into their training programs. There is much to be done in this area and it is a work in progress.

Network of Indigenous Cultural and Health Education

The importance of improving the knowledge base in Indigenous health of all health professionals cannot be underestimated, as that will help lead to improved understanding of issues when caring for Aboriginal and Torres Strait Islander women and this

will, in turn, translate into better engagement and hopefully and ultimately improvement in the well-known health disparities we see between Indigenous and non-Indigenous health. While one way to do this is to improve the training curriculum as mentioned above, Trainees and Fellows alike can embark on self-education in this field. To this end, I encourage members of the College to visit the Network for Indigenous Cultural and Health Education (NICHE) portal website (www.nicheportal.org), which was a RACS-led collaborative project (in which RANZCOG participated) to develop a website catering to the needs of College Fellows in accessing educational resources in Indigenous health in one convenient place. There is also a Fellows Forum to allow Fellows to communicate in a non-threatening, secure environment, allowing discussion of issues they come across while working with Indigenous patients.

RANZCOG Foundation

Research Scholarship & Fellowships in 2015

Prof Jonathan Morris
Chair, Research Grants
Committee

As in past years, the RANZCOG Research Foundation offered a number of scholarships for application in 2014 for research commencing in 2015.

Following the decision of the Board of Directors and members of the RANZCOG Research Foundation, as well as the College Board, to wind up the RANZCOG Research Foundation and transfer its operations within the College, scholarships previously offered by the RANZCOG Research Foundation now form part of those that will be offered by the newly established RANZCOG Foundation.

The RANZCOG Foundation is pleased to present this summary of the recipients and the research they are conducting in 2015.

Ella Macknight Memorial Scholarship, 2015–16

Recipient: **Dr Shakyalal Vidhura (Shavi) Fernando**
Institution: **Monash University**
Project: **'Melatonin and infertility: Can we improve outcomes of assisted reproductive technology – a placebo controlled randomised controlled trial'**

Dr Fernando is an adjunct lecturer in the Department of Obstetrics and Gynaecology at Monash University and PhD student at Monash University/Monash Health/Monash IVF. Dr Fernando has been awarded the Ella Macknight Memorial Scholarship for his project which will endeavour to determine whether melatonin has an effect on pregnancy rates and live birth rates in women undergoing in vitro fertilisation. Dr Fernando aims to determine how this effect occurs and what dose of melatonin is optimal.

Glyn White Research Fellowship, 2015–16

Recipient: **Ms Stella Liong**
Institution: **Obstetrics and Gynaecology Department (Mercy Hospital for Women), The University of Melbourne**
Project: **'Can dietary phytochemicals prevent the development of gestational diabetes?'**

Ms Liong is a postdoctoral fellow at the University of Melbourne (Mercy Hospital for Women) and has been awarded the Glyn White Research Fellowship for her project investigating whether phytochemicals will be effective in the management and treatment of gestational diabetes mellitus (GDM), and also whether these phytochemicals can also improve outcomes in both mothers and babies using a mouse model of GDM.

Luke Proposch Perinatal Research Scholarship, 2014

Recipient: **Dr Sebastian Hobson**
Institution: **Monash University**
Project: **'The role of melatonin in mitigating oxidative stress in pre-eclampsia'**

Dr Hobson is a senior registrar at the Department of Obstetrics and Gynaecology, Monash Health, and adjunct lecturer at Monash University's Department of Obstetrics and Gynaecology. Dr Hobson has been awarded the Luke Proposch Perinatal Research Scholarship for his study that will investigate whether the hormone melatonin is a useful treatment for oxidative stress in pre-eclamptic pregnancies. If the project is successful, it will potentially deliver the first treatment for pre-eclampsia.

Mary Elizabeth Courier Research Scholarship, 2015–16

Recipient: **Dr Luke Larmour**
Institution: **Monash University**
Project: **'Factors influencing the progression of high-grade cervical dysplasia to invasive carcinoma'**

Dr Larmour is an obstetrics and gynaecology registrar at Monash Health and adjunct lecturer in the Department of Obstetrics and Gynaecology at Monash University. Also a candidate for a PhD, at the Ritchie Centre, Monash Institute for Medical Research, Monash University, Dr Larmour was awarded the Mary Elizabeth Courier Research Scholarship for 2014, and has now been awarded funding for the second and third years of his three-year project examining how pre-cancer of the cervix progresses to cancer. Dr Larmour's project aims to use new technologies to find changes in the genes of pre-cancer and cancer cells. The importance and interaction of these genetic changes will be studied in a new mouse model of cervical cancer that will be developed. It is hoped that this will lead to identification of new targets for urgently needed new treatments for cervical cancer.

RANZCOG Fellows' Clinical Research Scholarship, 2015

- Recipient:** Dr Stefan Kane
- Institution:** The Royal Women's Hospital, Department of Perinatal Medicine
- Project:** 'Maternal ophthalmic artery Doppler waveform analysis in the assessment and management of pre-eclampsia'

Dr Kane is a RANZCOG Fellow undertaking Maternal Fetal Medicine subspecialty training and sessional obstetric consultant at the Royal Women's Hospital, Melbourne. Dr Kane has been awarded the RANZCOG Fellows' Clinical Research Scholarship for his project that aims to help improve care for women with pre-eclampsia; the commonest serious medical problem in pregnancy.

Through ultrasound imaging of a blood vessel in the eye, this three-year study will assess blood supply to the brain of women with pre-eclampsia before and after treatment. It is hoped that this information will help improve care for women with this condition.

Taylor-Hammond Research Scholarship, 2015

- Recipient:** Dr Victoria Nisenblat
- Institution:** The Robinson Institute, School of Paediatrics and Reproductive Health, Obstetrics and Gynaecology Department, the University of Adelaide
- Project:** 'Development and evaluation of plasma non-invasive diagnostic test for endometriosis'

Dr Nisenblat is a registrar in obstetrics and gynaecology at Lyell McEwin Hospital, South Australia, and visiting postdoctoral research fellow at the Robinson Institute, School of Paediatrics and Reproductive Health, at the University of Adelaide. Dr Nisenblat has been awarded the Taylor-Hammond Research Scholarship for her project that aims to develop and validate the accuracy of a non-invasive blood/urine test for a diagnosis of endometriosis. It is hoped that a reliable non-invasive diagnostic test for endometriosis will reduce diagnostic delay and the related morbidity and associated costs, with a substantial benefit to the whole community.

Scholarships continuing in 2015

Arthur Wilson Memorial Scholarship, 2014-15


- Recipient:** Dr Fiona Brownfoot
- Institution:** Mercy Hospital for Women
- Project:** 'Treating severe preterm pre-eclampsia with Pravastatin: An early phase clinical trial'

Dr Brownfoot's project, examining the administration of pravastatin to women diagnosed with severe early-onset pre-eclampsia to determine whether the drug can stabilise or reverse disease progression, and to assess its safety, will continue into 2015. It is hoped the drug can reduce the disease severity, allowing the pregnancy to continue until the baby is ready to be born.

Fotheringham Research Fellowship, 2014 - 2015

- Recipient:** Dr Ryan Hodges
- Institution:** Monash Institute of Medical Research, the Ritchie Centre
- Project:** 'Fetal therapy for congenital diaphragmatic hernia: A global partnership to translate surgical and cellular innovation'

Dr Hodges was awarded the Fotheringham Research Fellowship, 2014-15 for his project to test the hypothesis that human amnion epithelial cells (hAECs), when administered antenatally to fetuses with congenital diaphragmatic hernia (CDH), can reduce lung hypoplasia and abnormal pulmonary vasculature that leads to pulmonary hypertension, by promoting tissue regeneration and repair in utero.



FRANZCOG
LOGO GUIDELINES

As a means of recognising the dedication and professional service of its Fellows and their commitment to 'excellence in women's health', the College has developed a FRANZCOG Logo.

The FRANZCOG Logo can be used by College Fellows on office stationery, including letterhead and business cards, email signatures, websites and presentation slides to signify membership of the College.

The logo is available in various colour (full colour shown below) and file formats, and can be downloaded from the 'Member Services' section of the College website.



All Fellows are encouraged to consider incorporating the new FRANZCOG Logo into their stationery, whether hard copy or electronic.

WWW.RANZCOG.EDU.AU

Award-winning assignments

The inaugural RANZCOG Senior Secondary Students Women's Health Awards were recently presented in Australia and New Zealand.

The recipients of the inaugural RANZCOG Senior Secondary Students Women's Health Award were each recently presented with their award in the presence of their teachers and peers at two separate school ceremonies.

Eloise Sims, a Year 13 student from Queen Margaret College in Wellington, New Zealand, and Kate Cosman, a Year 11 student at Toorak College in Mount Eliza, Victoria, each received \$1000 for their outstanding achievement in literary writing on a women's health issue.

The award, open to students in their final three years of secondary school in Australia and New Zealand, was primarily introduced to increase the awareness within the education sector below tertiary level of the role and work of RANZCOG and is intended to be of relevance not only to students intending to study medicine at tertiary level, but also those with an interest in a variety of subject areas from science and health to law and politics.

The Award Committee was most impressed by the high quality of applications received from students on both sides of the Tasman, which included a range of fictional and factual pieces addressing women's health issues such as abortion, egg-donors, fertility, Indigenous Women's Health and prescription drug misuse.

According to RANZCOG Council Member, Dr John Tait, who presented Eloise with her award at Queen Margaret College,

Eloise's winning essay, 'Female Genital Mutilation, Ancient Practices Clash with Modern Medicine – Where to from Here?', was 'thoughtful, insightful and written sensitively about a very controversial subject'.

Queen Margaret College Principal, Ms Carol Craymer, was also deeply impressed with the maturity and skill shown by Eloise in writing about this culturally sensitive subject. 'To a young, educated New Zealander living in a country where every opportunity is available to women, the concept of female genital mutilation is alien. She researched this complex topic thoroughly and wrote an article which explored the various cultural perspectives that surround this practice.'

Eloise, who is interested in journalism and international relations, said the award has given her the opportunity to research and immerse herself in 'an issue of thankfully fast-growing concern around the world'.



From left: Helen Carmody, Toorak College Principal; Kate Cosman, award recipient; and RANZCOG President Prof Michael Permezel at the Toorak College presentation.



Dr John Tait presents Eloise Sims with her award at Queen Margaret College in Wellington.

'I was lucky enough to be able to interview the wonderful Nikki Denholm, Manager of the New Zealand Female Genital Mutilation (FGM) Education Program, which is run through the Department of Health. Nikki was immensely helpful and gave me such a balanced insight into the issue. I suppose the most difficult thing in writing about FGM was keeping an even perspective. I had to keep asking myself, "If I was an African woman, what would I think reading this?" As FGM is such an intrinsic part of some cultures, I really needed to step out of my own shoes and view the issue through their eyes to gain a proper understanding as to why it happens, and therefore how to prevent it.'

RANZCOG President, Prof Michael Permezel, presented Kate Cosman with her award at Toorak College and had high praise for her winning essay, which addressed the immensely important issue of obstetric fistula. 'It remains a common cause of long-term distress for women who give birth in countries with essentially no access to obstetric care. Although most common now in sub-Saharan Africa, it also occurs in some of the more remote areas of our near neighbours, including Papua New Guinea.'

Kate said researching and writing her winning essay has inspired her to try and make a difference to this serious women's health problem. 'I would really like to pursue this issue further by organising some sort of awareness and fundraising campaign within my school.'

At the Toorak College presentation, Prof Permezel also announced that from 2015 the prize will be named the Liam and Frankie Davison Award in memory of 'an enormously popular and devoted couple who were lost in the MH17 air disaster over the Ukraine.'

Liam Davison was a valued member of staff at RANZCOG, responsible for e-Learning, and Frankie a teacher at Toorak College for many years. The RANZCOG Board, with the support of Liam and Frankie's children, Milly and Sam, have decided to rename the award in recognition of Liam and Frankie's shared passion for nurturing and encouraging young writers, teaching and good literature, and in the hope that this will be the start of a meaningful legacy for Liam and Frankie.

It is anticipated the 2015 award will be advertised later this year, with the closing date for applications being 30 April 2015.

To read the winning entries, please visit the RANZCOG website: www.ranzcog.edu.au/womens-health/senior-secondary-students-women-s-health-award.html.

For further information, please contact:

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Women's Health Award 2013

Julia Serafin

Media and Communications

Senior Co-ordinator

The RANZCOG Women's Health Award 2013 University of Sydney recipient was Dr Samantha Sundercombe BSc(Adv) MBBS(Hons). Samantha is currently an intern at Liverpool Hospital, Sydney. Writing of what the award means to her, Samantha said:

'I am thrilled to be the recipient of the 2013 RANZCOG Women's Health Award at the University of Sydney. To me, the award means recognition for the effort I put into my Honours Research Project in women's health. This project was in conjunction with my usual medical studies in the second, third and fourth years of my four year course. Usually the eight-week elective period between third and fourth year is used for Honours projects, but the University allowed me to also complete elective terms in obstetrics and gynaecology in Kenya and Interventional Radiology at Cornell University in New York State. At the conclusion of the research project, my supervisor Prof Heather Jeffery OA, Chair of International Maternal and Child Health at Sydney Medical School, thanked me for my 'tenacity and tolerance!' Most importantly, this prize will help me achieve my goal of becoming an obstetrician and gynaecologist. Thanks to RANZCOG and to Dr Philippa Ramsay, who presented my award then spent an hour with me discussing the speciality as a career for a successful woman.'



Dr Samantha Sundercombe receiving her award from Dr Philippa Ramsay.

College Statements Update

July 2014

A/Prof Stephen Robson
FRANZCOG
Chair, Women's Health
Committee

The Women's Health Committee (WHC) reviewed the following statements in July 2014, which were subsequently endorsed by Council. College statements can be viewed on the College website.

New College Statements

The following new statements were approved by RANZCOG Council and Board in July 2014:

- Long Acting Reversible Contraception (LARC) (C-Gyn 34)

Revised College Statements

The following revised statements were approved by RANZCOG Council and Board in July 2014 with significant amendments:

- Diagnosis of Gestational Diabetes Mellitus (GDM) and Diabetes Mellitus in Pregnancy (C-Obs 7)
- The Use of Nifedipine in Obstetrics (C-Obs 15)
- RANZCOG Statement on Cervical Cancer Screening in Australia (C-Gyn 19)
- AGES/RANZCOG Statement on Tissue Extraction at Minimally Invasive Procedures (C-Gyn 33)

The following statements were approved by RANZCOG Council and Board in July 2014 with minor or no amendments:

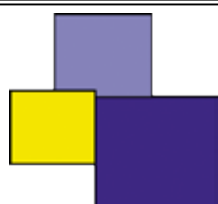
- Home Births (C-Obs 02)
- Warm Water Immersion in Labour and Birth (C-Obs 24)

- Provision of Routine Intrapartum Care in the Absence of Pregnancy Complications (C-Obs 31)
- Management of Monochorionic Twin Pregnancy (C-Obs 42)
- Alcohol in Pregnancy (C-Obs 54)
- Managing the Adnexae at the Time of Hysterectomy for Benign Gynaecological Disease (C-Gyn 25)
- Surrogacy in Australia and New Zealand (C-Gen 16)
- Guidelines for Patient Record Management on the Discontinuation of Practice (WPI 8)
- Joint RANZCOG/ANZCA Statement on the Provision of Obstetric Anaesthesia and Analgesia Services (WPI 14)

New College Statements under development

- Screening and Diagnosis of Adverse Pregnancy Outcomes

A full list of College Statements can be viewed on the Statements and Guidelines page of the RANZCOG website.



The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

EXPERT WITNESS REGISTER



Are you interested in joining the RANZCOG Expert Witness Register? Do you have the capacity to give expert medical opinion in the field of obstetrics, gynaecology or a subspecialty? Expert witnesses must have reasonable practice, scientific data and three years of practice in any of the following:

- General obstetrics
- General gynaecology
- Gynaecological oncology
- Obstetric and gynaecological ultrasound
- Reproductive endocrinology and infertility
- Maternal fetal medicine
- Urogynaecology

If so, you may like to consider joining our register.

Please visit www.ranzcog.edu.au/the-ranzcog/expert-witness-register.html for further information.

Staff news



Left to right: Karen Young, Glenda Hall and Dee Baines.

New appointments

Karen Young joined the College in October as an administration officer in the Queensland Regional Office. Having grown up in New Zealand, Karen moved to the UK and began her career in London. After three years, she moved to Australia where she worked for Allianz Insurance in the compulsory third-party claims department. More recently, she has run the administration side of her husband's plastering business.

Glenda Hall started with RANZCOG in October as co-ordinator for the Queensland Regional Committee. She previously worked in administrative roles for 20 years in the electricity industry, the highlight being for power giant ENERGEX as an executive assistant in a fast-paced environment. After taking time off to have children, she returned to the workforce in a role with Education Queensland as a note taker for hearing-impaired students.

Dee Baines started at the New South Wales Regional Office in September, and is responsible for the administration of events, education and training. She brings to the role experience gained in her previous positions as office administrator and flight attendant. Dee has recently completed a Diploma in Human Resources. In her spare time she is involved in Hands Across the Water, an Australian charity set up after the Boxing Day tsunami that supports at-risk Thai children and their communities.



Left to right: Lisa Del Din, Blessy Mannil and Katharine Ebbs.

Lisa Del Din commenced as senior assessment co-ordinator at RANZCOG in August 2014. Before joining the College, Lisa worked in secondary education as a science teacher for 19 years and has experience in a variety of leadership roles. Lisa has a Bachelor of Science and a Graduate Diploma in Education.

Blessy Mannil started at the College in October, as the nuchal translucency administrative officer, part of the Women's Health Services team. Previously, Blessy was a project assistant at the Murdoch Children's Research Institute, based in Parkville.

Katharine Ebbs joined the College in October this year as elearning senior co-ordinator. Katharine's background is in elearning, training and teaching in the tertiary, community and secondary sectors. In the last four years Katharine worked as the elearning manager at the Australasian College for Emergency Medicine. She holds a Bachelor of Arts, a Graduate Diploma in Education and a Master of Educational Studies (Educational Computing), and is a Certified Associate in Project Management.

Departures

Wendy Morrison resigned from her position in the Queensland Regional Office in August. After nearly nine years in the role, Wendy is seeking other challenges. We wish Wendy all the very best for the future and thank her very much for her efforts.

Andrew Haxton, after 13 years with the College, resigned from his position as ICT manager in November to return to his native New Zealand with his family. We thank Andrew for his many years' service and wish him all the very best for the future.

Elise Sturgess resigned from her position as examinations administrator, leaving the College in early December, to travel. We thank Elise for her contribution to the College, firstly in the Office of the President and CEO and then more recently in Assessment Services.

Notice of Deceased Fellows

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

Dr Carlos Alberto Yudi, QLD, on 6 May 2014
Dr Terence Cody, NSW, on 30 August 2014

Obituary

Robert James Furlong McInerney
1918 – 2014

Robert James Furlong McInerney, Bob, was born in 1918, in Haberfield, New South Wales. He was the second of eight children to Jim McInerney and Mary Lehane – an Australian father and an American mother.

He was educated at St Joan of Arc Primary School, Haberfield, and De La Salle Secondary School, Ashfield. These were the depression years and his father was going to withdraw Bob from school when he completed the Intermediate Certificate; it was only when the school intervened with the offer of a Scholarship to complete the Leaving Certificate that his father relented. Bob was School Dux in 1936, and won an Exhibition to Sydney University to study medicine.

Bob excelled at university, gaining a distinction in anatomy in third-year medicine. He graduated MBBS (Honours) in 1942, coming third in his finals. He shared the Brown Craig Prize for operative surgery and shared the CLIPSHAM Prize in surgical anatomy. Later, at St Vincent's Hospital, he was awarded the Dielthem Prize in medicine and shared the Coppelson Prize in surgery.

Bob saw active service in World War II, serving in New Guinea and Borneo. He was recommended twice for the Military Cross, but it was not awarded. He was very proud of a written testimonial he received following the war from one of the troops titled: Testimonial to a Good Soldier.

The war was a defining period in Bob's life: he promised, if he survived, he would spend the rest of his life helping others. Following the end of the war, Bob had stints at Crown Street Hospital and at St Vincent's as a registrar. He then travelled to the UK and worked at Jessup Hospital in Sheffield, where he gained his MRCOG. Subsequently, he spent time at St Thomas' Hospital in London where he gained his FRCS in general surgery. Bob then spent three-and-a-half years in England. Later medical honours gained were the FRACS, FACS, FRCOG and FRACOG.

In 1952, Bob began his practice at 231 Macquarie Street and he remained in the practice there for the remainder of his professional life. It was in that year that he married Betty Rose Stormon, a marriage that extended over 50 years. Dr and Mrs Stormon, Betty's parents, were great supporters of Bob as he went about establishing a successful career as an obstetrician and gynaecologist. Bob was the first doctor in Australia and the third in the world to perform a blood transfusion on a baby in the womb. He delivered around 27 000 babies in his career. Although not blessed with children of his own, Bob brought happiness to thousands of families in his work. In time, Bob became an Honorary at St Margaret's, St Vincent's, Lewisham and the Mater, all in Sydney. Later, he became Chair of the medical staff and Chair of the Hospital Board of St Margaret's Hospital.

In 1967, Bob was appointed to the Executive Council of the Federation of International Gynaecologists and Obstetricians (FIGO). In 1968, he worked overseas with international specialists, including Prof Kobayoshi, obstetrician to the Empress of Japan. He was a visiting professor in Atlanta, USA; Bangkok, Thailand; Buenos Aires, Argentina; Fiji; and the Philippines. He became a member of the Sovereign Military Order of Malta in 1975.

From 1980–86, Bob was Chair of the NSW State Committee, the Royal Australian College of Gynaecologists. He was a member of the Medical Board of NSW. He was a Past-Master of the Medical Guild of St Luke and was a Past-President of Right to Life Australia.

In his eighties, Bob was involved in outreach activities in the Darlinghurst area and he was, for a time, a Eucharistic Minister until age caught up with him. He was recognised for his voluntary activities by being made a Member of the Order of Australia and a Companion of the Most Distinguished Order of Saint Michael and Saint George.

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