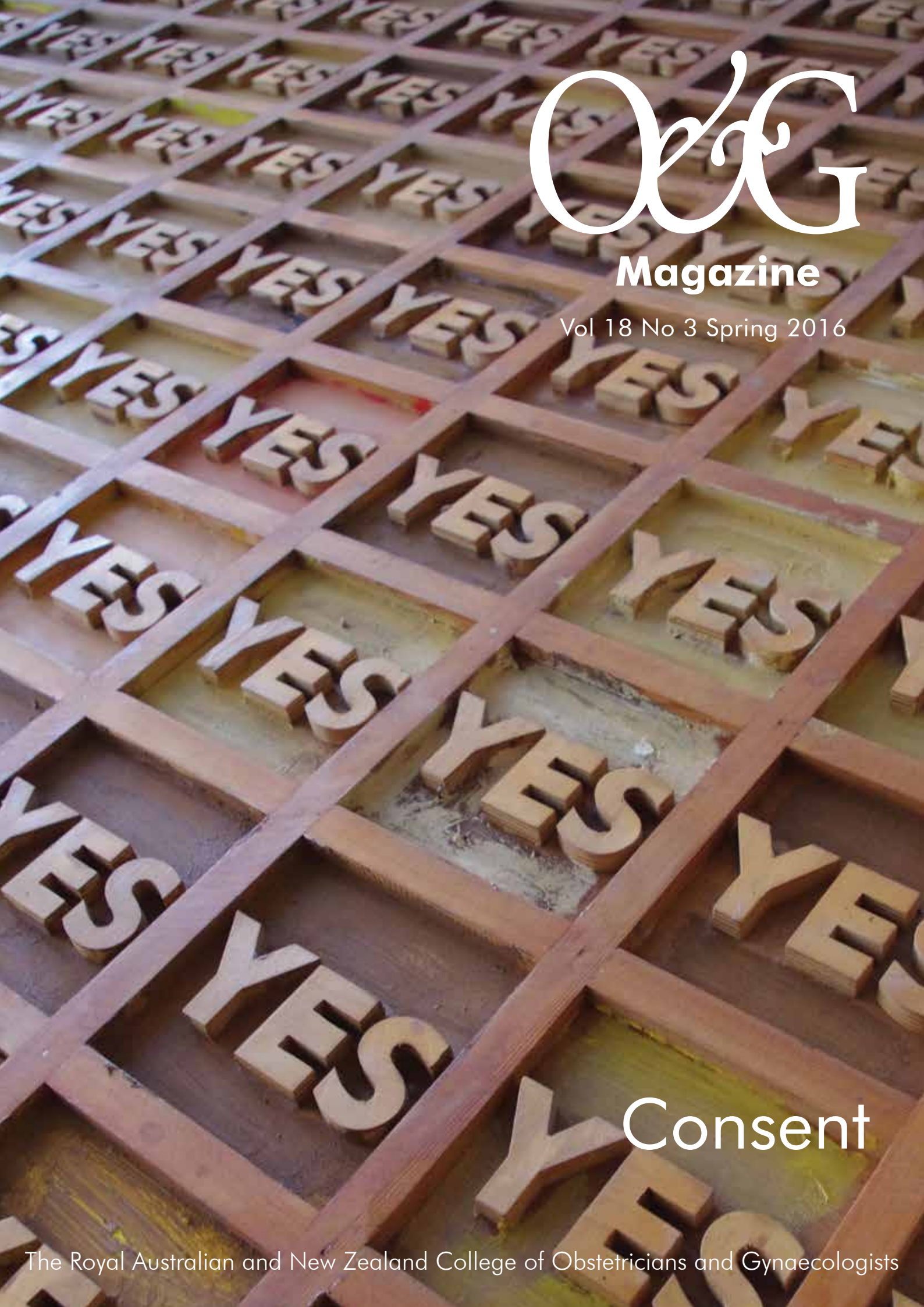

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Consent

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

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The Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Excellence in Women's Health

From the President

Prof Michael Permezel
President

This is my 16th and final President's report. I hope the readership will excuse an attempt to reflect on some of the key challenges that lie ahead for the College, its members and the women they serve. While much of the below has been discussed in previous reports, the challenges remain.

Women's health

The fallacy of 'no evidence'

It has been a source of great frustration to repeatedly hear eminent Fellows indicate they follow a certain practice even though there is 'no evidence'. What they actually mean is that there has not been a randomised controlled trial (RCT) to support that line of management; they certainly are not operating in an evidence vacuum. In fact, the vast majority of sound clinical management is not based on RCTs, but rather, the best available evidence to guide practice in those situations, assimilated by experienced clinicians able to apply that evidence. An RCT will often be the worst form of evidence to apply, given the impossibility of an RCT assessing low-frequency (but clinically important) outcomes. If such an RCT is attempted, it is likely to be compromised by heterogeneity of populations, bias, the Hawthorne effect and protocols that do not necessarily reflect clinical reality. We do practice based on evidence and the College has a key role in gathering experienced clinicians to synthesise all the available evidence and make recommendations for clinical practice. The growth in the women's health statements and the recent expansion into patient information is a credit to all involved in the Practice and Advocacy department of the College.

FRANZCOG training

Surgical procedure numbers must be linked to placement of trainees

It has been alarming to hear that many Fellows (who should know better) apparently believe that the number of accredited registrars at their hospital should equate to the number of registrars needed to fill the on-call roster. This fallacy has no credibility whatsoever. The Australian Medical Council (AMC) was very clear in its direction to the College at the time of the last accreditation visit: accredited training places must be linked to the available training. Analysis of trainee logbooks from 2015 indicates that, while many hospitals are providing excellent training, there are some health services that appear to prioritise clinical 'service' and have neglected surgical training. While no one disputes the increasing role of simulation and training quality, quantity is needed as well.

How can the 'clinical service' commitments be met in hospital where surgical training deficiencies mean that FRANZCOG trainee numbers need to be reduced?

The 'registrar in training' model is a relatively cheap way of providing a 24-hour roster, providing that the volume of trainee gynaecological surgery justifies those positions. Those hospitals that are not meeting this challenge have a number of strategies available to them, but inevitably at some cost. Trainee

gynaecological surgical opportunities may be increased by: more gynaecological surgical lists, employing consultants who are pleased to use all public cases for registrar training or dispensing with an overseas Fellow who is taking precious procedural work away from local trainees.

Where an increase in gynaecological surgery training proves impossible, it may be necessary to make better use of the pre-vocational workforce or new Fellows. 'Career medical officers' (career hospital registrars) may have been at one time aspirational, but are rapidly becoming a workforce necessity. The College will need to work with hospitals and other colleges to make this role a viable and prestigious career. Those that see ongoing dependence on International Medical Graduates (IMGs) to fill these positions are likely to be disappointed. With 3700 Australian medical graduates annually (compared to 1400 a decade ago), there is appropriately considerable pressure on government to reduce the intake of IMGs in favour of increasing employment opportunities for our own graduates.

Bullying and harassment

The College now has interim results of its bullying and harassment survey and I thank those that contributed. It is disappointing to learn that, as in other medical colleges, a substantial number of trainees have experienced bullying. Every Fellow and trainee must adopt a 'zero-tolerance' approach to bullying in the workplace. All should critically reflect on their own behaviours and those of their colleagues. Fellows are encouraged to use opportunities to upskill in this area, using available face-to-face and online resources.

Selection for FRANZCOG Training

At the time of writing, New Zealand selection is complete and Australia has just completed interviews of approximately 170 of the 226 applicants for 80 training positions in 2017. Unfortunately, many outstanding potential future specialists will miss out on selection, largely because there are simply too many good applicants.

> 'Many outstanding potential future specialists will miss out on selection, largely because there are simply too many good applicants.'

Institutional references

All who have read these reports over the last four years will be aware of my obsession that workplace performance before application must be allowed to influence the selection process. Given that applicant-nominated referees are almost invariably very good, only institutional references are able to discriminate between applicants on the basis of workplace performance. Institutional references allow the selection process to incorporate important traits not otherwise captured in selection, including surgical aptitude and professional attributes such as diligence and reliability. It is plausible that the future workplace bully may already have demonstrated unwelcome professional attributes prior to selection. In future, a quantum reflecting both negative and positive prevocational behaviours must be included in the selection score.

Rural workforce
It is perhaps fitting that my final comment should be on the great workforce challenge for all colleges: how to accomplish a better rural distribution of Fellows and Diplomates. There is no single solution. The Medical Deans of universities must do more to select those medical students most likely to practice in rural centres (for example, even greater reward for rural schooling). The College must continue to advantage those trainees more likely to practice rurally in its selection process. Rural training must be optimised at core and advanced levels. Finally, maximal support must be given to rural practitioners through initiatives like Rural LAP and funded CPD initiatives. My personal thanks goes to Dr Tony Geraghty who has worked tirelessly over the last four years in all these areas as Chair of the Provincial Fellows Committee.

> 'The Ninth RANZCOG Council concludes in November and the Tenth Council begins anew. I would like to formally thank all College staff, an outstanding Board, the Council and its hard-working Committees. A special thanks to those that have provided me with magnificent support, with sage advice and wise counsel.'

Conclusion
The Ninth RANZCOG Council concludes in November and the Tenth Council begins anew. I would like to formally thank all College staff, an outstanding Board, the Council and its hard-working Committees. A special thanks to those that have provided me with magnificent support, with sage advice and wise counsel. I will resist naming them, but they know who they are!

My best wishes go to Prof Stephen Robson, the new Board and the new Council.

From the CEO

Alana Killen
CEO

Last year, the Royal Australasian College of Surgeons (RACS) made headlines around Australia and overseas when the ABC's Four Corners program reported on bullying within surgery,[1] effectively lifting the lid on a well-known problem within Australian hospitals. As a result of this publicity, RACS instigated a large-scale investigation into the extent of the issue, which led to the establishment of a plan of action to address the endemic and deep-seated culture existing within the speciality.[2] Although now proactively tackling the issues,[3] the reputational damage caused has not been insignificant and the impact has reverberated across the entire medical college sector in Australia and New Zealand.

Although much evidence has been produced in the UK regarding bullying in medicine[4] there has been little research undertaken in Australia or New Zealand. The research that has been undertaken suggests that the problem is replicated here[5] with similar themes emerging.

In 2014, the Royal College of Obstetricians and Gynaecologists (RCOG) conducted a survey to explore the incidents of bullying and undermining among O&G consultants in the UK.[6] That survey resulted in a 28 per cent response rate, of which 44 per cent responded that they had been persistently bullied or undermined. This represented 14 per cent of the RCOG consultant workforce. The reported impact on professional and personal life spans a wide spectrum, from a loss of confidence to depression, sleep disturbance and suicidal ideation. Over half of respondents reported problems that could compromise patient care.

Earlier this year, RANZCOG disseminated a survey to Fellows and trainees in order to identify the extent of bullying and sexual harassment within the O&G workforce in Australia and New Zealand. For the purpose of the survey, the following definitions were provided: 'Workplace bullying is defined as repeated and unreasonable behaviour that creates a risk to health and

safety, and; Sexual harassment is defined as an unwelcome sexual advance, unwelcome request for sexual favours or other unwelcome conduct of a sexual nature which makes a person feel offended, humiliated and/or intimidated, where a reasonable person would anticipate that reaction in the circumstances'.[7]

The survey was sent to 2149 Fellows and 701 trainees; of this number, 659 Fellows and 265 trainees responded – a response rate of 32 per cent. Of the total responses received, 60 per cent (552) indicated that they had been bullied in the O&G workplace. This represents 19 per cent of the combined Fellow/trainee RANZCOG workforce. In response to the question, 'what was your role when the behaviour occurred', 71 per cent indicated that it occurred while they were a trainee; with 34 per cent stating it had happened as a consultant (respondents were able to select more than one category). The behaviour occurred primarily in the operating theatre (51 per cent) with 47 per cent indicating it had happened in the birthing suite. The person primarily responsible was identified as a senior (>10 years practice) O&G consultant (69.5 per cent), with midwives (28.1 per cent), and junior consultants (27.8 per cent) the other main groups identified. When asked if respondents had been personally subjected to bullying in the O&G workplace in the last three years, 60 per cent (299) indicated that they had.

When asked if they had been personally subjected to sexual harassment, 12 per cent of respondents indicated that they had, with 88 per cent stating that they had not (from 861 responses). This behaviour occurred mostly when participants were trainees (74 per cent) with the person responsible generally a senior O&G consultant (76.8 per cent) and male (91 per cent). In response to the question asking if participants had observed bullying or sexual harassment in the O&G workplace, of the 851 respondents to this question, 60 per cent stated that they had. When asked if they had reported the behaviour, only 24 per cent responded in the affirmative. The reasons given for not reporting were generally related to a fear of compromising career prospects (68 per cent) with 56 per cent expressing the concern that it would make the situation worse.

The major themes emerging from the survey are very similar to those reported from other surveys, both in Australia/New Zealand and in the UK. These relate to humiliation and belittling behaviour (including shouting) that is generally perpetrated in the presence of others, including patients, peers and other health professionals. It was reported that this practice of 'teaching by humiliation' was common among some senior consultants and likely considered an appropriate and effective teaching method. When responding to the question about sexual harassment, respondents most commonly identified innuendo/propositioning (61 per cent) with 13 per cent indicating they had been subjected to unwelcome/inappropriate touching.

So what do we make of this survey and what does it tell us about the culture of O&G in Australia and New Zealand? Although the numbers were proportionally small, there were still more than 100 people who reported being victims of sexual harassment – any number would be unacceptable and RANZCOG needs to clearly state that such behaviour will not be tolerated under any circumstances. Although the perpetrator may consider their 'innocent remarks, jokes or good-natured teasing' to be inoffensive, such behaviour may be deeply disturbing and intimidating to those in less-powerful positions.

A number of respondents to the survey suggested that some trainees were not 'tough' enough and needed to be more resilient and less sensitive. There are doubtless some instances where there has been an over-reaction to well-intended if not poorly executed feedback or remarks, however if the general principles of respectful communication are observed, these instances should be significantly diminished. Respectful communication requires providing constructive feedback in private and not engaging in displays of public humiliation. It also requires greater awareness of how behaviour or comments may be perceived by others. As with most theories, pedagogical approaches have changed over the years and methods that were once considered effective and appropriate are now found to be less so. However, recipients should also be aware that constructive feedback or performance management is not the same as bullying.

The RANZCOG Board is committed to addressing the issues arising from the survey and will be initiating a number of strategies including:

- improving complaints handling process;
- developing education and training resources (including how to give and receive feedback);
- enhancing accreditation standards; and
- increasing support for those experiencing bullying or harassment.

The survey has shown that RANZCOG has challenges ahead with regard to cultural change. However, the survey also provides important information and guidance regarding the training and education needed and the most effective way to address the issues arising. Although these matters are not confined to O&G, it is the College's responsibility to lead the changes needed within the profession and proactively promote inclusive, respectful and safe workplaces that ultimately lead to better outcomes for patients.

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RANZCOG PATIENT INFORMATION PAMPHLETS

COMING SOON

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- Aligned with RANZCOG statements and guidelines
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The Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Excellence in Women's Health

Editorial

Dr Gillian Gibson
FRANZCOG

Informed consent the process whereby a patient with the capacity and competence to do so, having been given sufficient information, makes a reasoned decision whether to agree or not to a proposed treatment or procedure.

Consent may be given orally or in writing, but filling out forms is not as important as the adequate exchange of information, so that an informed decision can be made. Good communication is integral to this process, as is imparting the concept of risk without paralysing your patient with fear of the consequences. Language barriers, unconscious or intellectually disabled, or the deceased patient, present particular challenges in obtaining informed consent. The competency of minors is important in O&G practice with regard to contraception and abortion where the Gillick principle is applicable (see page 19).

The question of patient consent exploded into the public arena in New Zealand with the Cartwright Inquiry[1]. The Inquiry was set up in 1987 to investigate the treatment of women with cervical carcinoma in situ over a 20-year period at National Women's Hospital in Auckland. It concluded that the management of the women by Prof Green had been unethical. Firstly, patients were placed at unacceptable risk. Secondly, none of them knew their 'watch and wait' clinical management was any different to accepted practice at the time, nor had they expressly agreed to participate. In this issue of *O&G Magazine*, Rosalie Grivell outlines the principles of bioethics, including safeguarding research participants, and reminds us of the Helsinki Declaration (1964) that requires full explanation and freely given consent to clinical treatment (see page 22).

The current expectations around informed consent for medical students and supervising doctors in clinical settings are addressed by John Allen (see page 26). In some instances, explicit consent obtained in writing is indicated, particularly where the patient is to be anaesthetised. When I was a medical student in the mid-1980s (prior to the Cartwright Inquiry) our clinical group was instructed to attend a general surgical operating list. Eight of us lined up ready with gloves on, the male patient anaesthetised and positioned in lithotomy. One by one we did a rectal examination and felt a hard, craggy mass. This opportunity was invaluable for us to learn to better recognise a rectal cancer, but a large student group in theatre would be unacceptable today.

In this issue, Brett Daniels reminds us of the process required for the introduction of new products, drugs and procedures into clinical practice (see page 52). In June, a Health Select Committee of the NZ House of Representatives made a number of recommendations[2], which included a centralised surgical mesh registry and that medical collages review best practice around informed consent for mesh procedures. A recent RANZCOG communiqué[3] released in response to the Health Select Committee's report is recommended to our readers, which offers guidance about the future use of mesh in gynaecology.

A landmark ruling in the UK Supreme Court in 2015 relates to shoulder dystocia in a diabetic mother resulting in a child with severe disabilities. [4] There were red flags in the antenatal history and the court agreed the mother ought to have been given advice about the risks of shoulder dystocia with a vaginal birth, and the alternative of delivery by caesarean section. As a consequence of this case, RCOG is convening a meeting to debate the need to fully inform women of the risks of vaginal birth. Two articles in this issue explore the concept of obtaining consent from all women planning to give birth vaginally. Pelvic floor injury can impact significantly on quality of life. Peter Dietz challenges us to consider fully informing women of these risks when discussing mode of birth (see page 40).

Informed consent is fundamental to the safe practice of medicine. There are two RANZCOG College statements related to obtaining consent for treatment, each one specific to Australian[5] or New Zealand[6] jurisdictions. It is necessary as medical practitioners to be familiar with the legal principles and guidelines that apply to the state/territory/country where you are practising. Our respective defence organisations give clear guidance in this issue of consent.

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How to communicate risk

Dr Denys Court
MBChB, LLB, MRCOG, FRANZCOG, FACLM

The concept of health risk is difficult for the public to understand. A patient's perception of risk arises from the way risks are communicated to them, the rapport they have with their doctor and what they bring to the conversation: personal values, previous experience, family history and cultural norms.[1] Such perceptions affect not only the extent to which a treatment will be acceptable to a patient, but also their level of dissatisfaction if complication occurs. This article deals with influences on decision-making from the way we frame risk and benefit in our discussions with patients about treatments and procedures.

This issue is heightened in today's health environment where advances in technology make more advanced and complex treatments possible. Discussion about risk carries more importance in situations that are elective (where the status quo is an option); where there are multiple treatment options, especially in the absence of medical consensus; or where there is high potential for an adverse outcome. In such situations, how we discuss risk is perhaps the most important component of the consenting process. Data uncertainty is one of the challenges in risk communication.[2]

Uncoupling risk and benefit

Many of our patients may see risk and benefit as inversely proportional, if risk is low then benefit must be high, and vice versa. As perceived risk increases, perceived benefit may decrease. Metaphorically, they see risk and benefit as a 'seesaw'. This can set up unrealistic expectations of benefit on one hand or underestimating potential for benefit on the other. In reality, risk and benefit are more akin to two lifts that can move up or down with a degree of independence from each other.

We need to uncouple risk and benefit in consenting conversations with our patients. This can be done by discussing the potential benefits of a treatment, determining which benefits a patient attributes value to, and then determining whether those perceived benefits remain valued in light of the risks of that treatment. Whether benefits continue to be valued in light of the risks can be significantly influenced by the way we frame risk.

Framing of risk

The way information is presented can have significant effects on decisions made.[3] Where patients considering angioplasty were randomised as to how risk was 'framed' and shown a brief video that stated '99 per cent of patients undergoing this procedure do not have any major complications' (positive framing), or alternatively 'one in 100 people who undergo this procedure suffer a complication' (negative framing), 52 per cent of the positively framed group stated they would definitely or probably undertake the procedure, falling to 27 per cent of those for negative framing.[4] To understand this, with the first statement the probability of a good outcome is accented; as if the patient's unconscious thought is 'surely I'll have a good outcome'. In contrast, with the second statement, the focus is on the possibility of an adverse outcome; the subconscious thought being 'that could be me'. In short, we are shifting the patient's reference point from a perception of benefit to one of harm.

Furthermore, there is the possibility that how we frame risk can be magnified by the degree to which individual patients may be risk-accepting or risk-avoiding; that is, their inherent risk-framing. A patient who is risk-avoiding by nature is very unlikely to choose a treatment where the risk has been framed negatively.

In order to minimise the impact of both practitioner and patient framing of risk, we need to consider providing 'balanced framing'. As an example, stating 'for this procedure, 99 per cent of people do not have any serious complication; however, one per cent do' is balanced and with subsequent conversation, it is likely that the degree to which the patient is risk-accepting or avoidant may be revealed. Further discussion can then tease out why the patient has concerns about risk that seem greater than other patients.

Another example of framing is that of 'loss or gain' framing, where perceived losses in not acting are revealed in order to motivate a treatment action as well as, or rather than, perceived gains likely to result from that action.[5] Consistently, loss-framing has been shown to be more effective in increasing uptake of an action than gain-framing.[3] Again, being aware of both techniques can be of benefit. For example, where it seems to a doctor that a patient is unexpectedly reluctant to consider a low-risk treatment readily accepted by most patients, exploring why there is reluctance (such as previous experience or cultural norms) and then loss-framing the discussion may increase uptake.

Other techniques to describe risk

It is important to use plain language in description of risk and to take into account how our patients understand those descriptions, by moving our terminology and conversational style toward their own.

Studies have looked at whether using verbal or numerical descriptors of risk can affect decision-making. For example, in a study of the use of European Union risk descriptors, words such as 'common' (1–10 per cent frequency) and 'rare' (0.01–0.1 per cent frequency) were provided. Use of the verbal rather than numerical descriptor led to overestimation of the chance of harm, with increased wariness of accepting a treatment action than when numerical descriptors were used. Accuracy of immediate recall is also better with numerical descriptors.[6]

Though there are few significant studies on this comparison, suffice it to suggest that verbal descriptors alone are best avoided. A statement incorporating both numerical and verbal descriptors seems best.

Inclusion of visual representation may also improve understanding. Written information is a useful reinforcement of risk realities, as they are for other aspects of consent.[7] College information pamphlets are excellent examples. Such decision aids may improve accurate risk perception when probabilities are included.[8]

It is also apparent that the higher the numerator in a risk ratio, the higher the perceived risk.[9,10] Thus, 1:100 and 1:10 may not seem very dissimilar to those patients with low numeracy skills, whereas 'one in 100' and 'ten in every 100' will provide an improved understanding of the relative risks.

Presenting more data points in a risk discussion appears to lead to more cautious treatment decisions.[1] Therefore, we need to be careful that we show some judgment as to which risks are more relevant to our patient's decision-making. Determining the number of data points we present can be based on our professional consensus on one hand and the patient's value system on the other. If a patient seems too ready to accept a procedure, seemingly without due consideration to risks and benefit, adding data points may introduce some due caution.

Summary

In communicating risk with our patients, 'multiple complementary formats' best enable our patients to make a choice that they will continue to believe is right for them.[11] To facilitate this, we need to remember:

- It is essential that we normalise risk for our patients by discussing the risks related to all their options, including the risk for taking no therapeutic action.
- Use both positive and negative framing.
- Loss-framing may be useful.
- Use simple numerical data, verbal descriptors and visual aids to enhance understanding.
- Use the same denominator when comparing risks.

Finally, it is important that the patient receives all the risk and benefit information that satisfies them, and we must also ensure that they understand this information and assess their emotional response.

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The importance of saying no

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Qui Tacet Consentire Videtur – She who is silent appears to consent.

We all appreciate consultations where the patient is accepting of the advice offered and has few questions. However, silence during the process of consent may be no longer as 'golden' as it once was. It may be a dangerous prelude to a medicolegal action which was, in retrospect, totally preventable.

Autonomy in law means the right to self-determination. Even when a patient refuses valid life-saving measures, their right to do so must be respected. Consent to a surgical procedure requires that the recipient understands the nature of the procedure and its ramifications. Fully informed consent may seem like an unrealistic ideal, however, risks relevant to a particular patient must be ascertained and discussed; these are the 'material risks'. To reflect this, the term 'valid consent' is replacing 'informed consent'. Obtaining valid consent requires time and patience; one consultation may not be sufficient. Handing the patient a treatment information pamphlet and recording its receipt does not constitute adequate explanation and patient understanding.

Medical negligence

For a successful claim of negligence against a doctor, the plaintiff must establish the following:

- the doctor owed the plaintiff a duty of care;
- the doctor breached the duty of care, that is, failed to meet the required standard of care;
- the breach of duty caused the plaintiff to suffer injury;
- the injury was foreseeable; and
- the injury is of a kind that is compensable at law.

Issues of inadequate consent go to the standard of care provided. The legal test relating to the provision of information differs from the test regarding reasonable diagnosis and treatment, which is in the practitioner's domain. The key difference is that the patient decides what is reasonable information about a proposed procedure based on her 'needs, concerns and circumstances'.[1] Reasonable diagnosis and treatment, on the other hand, is determined by the practitioner whose standard must meet that of an ordinary competent peer professional practising in that field. The High Court has held that 'no special medical skill' is required to disclose medical information to a patient and therefore it is the Court who will decide if the provision of information met the needs of the plaintiff.[1]

Disclosure of risk

Under the common law of trespass, patients have a right not be subjected to an invasive procedure without consent, unless an urgent life-saving intervention is required.[2] Trespass is a legal term meaning a deliberate physical interference with a person or their property without permission. Ethical medical practice also requires that consent to a procedure is obtained as part of the duty of care. The prerequisites are that the patient has sufficient mental capacity to understand the explanation and that the explanation is sufficiently comprehensive to enable voluntary consent to be given or refused.

Material risks are those that for a particular patient are relevant and important and that a practitioner knows or should know would influence a patient's decision to consent before proceeding. For example, if a patient wants to ensure that no damage is sustained to a functional eye by a procedure to the other blind eye, then that is 'material'[1] even if the risk is remote.

In the UK, the standard of risk disclosure is to conform to the professional standard of one's peers.[3] Australia has chosen a slightly different path with the introduction of the Civil Liabilities Act 2002, whereby the practitioner cannot be held liable if it can be established that they acted in a manner that was accepted by a body of peer professional opinion as competent professional practice. That need not be a widely accepted opinion, but must be rational (NSW, Qld, SA, Tas) or reasonable (Vic) or not so unreasonable that a reasonable health professional would have rejected it (WA).[4]

Understanding risk

Informed consent means legally that 'an individual has been given full or adequate disclosure'.[5] If 'full' was interpreted to mean that every conceivable risk was canvassed with the patient, then that would be impractical. Valid consent infers that the patient has been informed of the nature and purpose of any proposed treatment, as well as the likely outcome(s).This includes any significant potential adverse outcomes, and the likely result of not proceeding with the proposed treatment. All this is necessary so that an individual can make an informed decision. Alternative treatments should be discussed. The operative experience of the proceduralist for the proposed operation might also be relevant to the patient.[6]

An oft-neglected part of the consent process is whether the patient truly appreciates the risks explained. Even if these are correctly appreciated, there may be a false assumption by the patient that if these risks eventuate, they can always be quickly and completely rectified. In doing so they may be underestimating their significance. For example, the patient who is told that a cut ureter sustained at hysterectomy can be re-joined, may not appreciate the long process

of recovery, the prolonged use of ureteric stents or the subsequent bladder dysfunction and urinary tract infections that may follow. Similarly, the catastrophic risks of a rubella embryopathy are not simply solved by the supply of a 'glass eye, an artificial heart valve and a bionic ear' to the affected infant, as one pro-life obstetrician once claimed.

The National Health and Medical Research Council Guidelines for Medical Practitioners on Providing Information to Patients[7] emphasise the importance of patient comprehension of the information provided. This may require repeated explanations that are free from jargon, giving the patient sufficient time to digest the information provided. Supplementary diagrams and written information may aid understanding and several patient encounters may be necessary.

Obstetric risk

Claims of negligence may arise when an obstetric patient asserts that her obstetrician failed to provide her with sufficient information to make an informed decision regarding management. This might occur where the obstetrician chose not to reveal information received in an ultrasound report describing suspicious 'soft signs' of aneuploidy and decided not to undertake further investigations. The test of disclosure of obstetric risk is the degree of detail that would be required by a reasonable person. Obstetricians need to determine what each 'reasonable' mother expects. What is reasonable to one mother may be completely inadequate to another patient who perhaps has a personal or family history of fetal anomalies. The test in Rogers[1] is relevant when risks that the doctor knew or ought to have known would influence the patient's decision.

Presenting information on risk

In the UK, the RCOG[8] has offered a rule-of-thumb for interpreting risk (see Table 1). This may make risk meaningful to some patients who struggle to interpret absolute numbers; however, material risk is the real issue and may not be quantifiable.[6]

Table 1. The RCOG guidelines for interpreting risk.

Term	Numerical risk	Colloquial equivalent
Very common	1/1–1/10	A person in the family
Common	1/10–1/100	A person in the street
Uncommon	1/100–1/1000	A person in the village
Rare	1/1000–1/10 000	A person in a small town
Very rare	<1/10 000	A person in a large town

Consent in special circumstances

The Guardianship Tribunal

For minors or other patients who lack mental capacity, consent for certain procedures cannot be given by parents or guardians. This particularly applies for procedures that might produce permanent sterility, such as tubal ligation or hysterectomy, or even reversible sterility, such as the administration of Depo-Provera. For such decisions, a Guardianship Tribunal is the necessary decision-maker. This follows the judgement in Marion's case[9] where parents sought to have a hysterectomy performed on their disabled child.

When a fetus may suffer

The fetus has few legal entitlements until birth. Until a fetus is born, it is not considered a 'person' in Australian law.[10] This follows the sentinel UK case in which Sir George Baker held that: 'The fetus cannot in English law, in my view, have any right on its own until it is born and has a separate existence from its mother.'[11] The principle of respecting a mother's autonomy may mean that the fetal interests are overridden.

Female sterilisation

Consent for female sterilisation in Australia previously required the consent of the husband, but this was omitted because of human rights considerations. Spousal consent is still required in countries such as Brazil, Chile, Ecuador, Guatemala, Honduras, Japan, Niger, Taiwan, Rwanda and Turkey. In Finland, Hungary and Switzerland, the spouse is required to be informed of the proposed female sterilisation by the applicant.[12]

There has been recent controversy over the patient's right to choose tubal ligation, even in their early 20s.[13] Many gynaecologists would adhere to previous advice that sterilisation not be done until the patient is at least 30 years of age. Twice the expected rates of requests for reversal were made when sterilisation was performed in younger patients.[14] However, the expected rates are only approximately six per cent.[15] Controversy has arisen because it challenges patient autonomy.

The Federation of International Gynecology and Obstetrics recommends that: 'No woman may be sterilized without her own, previously-given informed consent, with no coercion, pressure or undue inducement by healthcare providers or institutions.'[16]

Two important considerations that should be discussed are the failure rate of the proposed procedure and the relative difficulty of tubal reversal. Alternatives to female sterilisation that are available to the couple, including vasectomy and other reliable long-term methods of contraception, should be discussed with the patient.[17]

Cosmetic vaginal surgery

The Medical Board of Australia (MBA) has recently expressed concern regarding the validity of a young person's consent for cosmetic surgery, including genital surgery. The worry is that such individuals may be motivated by unrealistic expectations of their appearance or attribute social problems to cosmetic defects. In other words, some young women can be subtly coerced into undergoing cosmetic procedures by the influence of their peers or by their surgeon. The MBA has proposed three-month 'cooling off' periods for patients less than 18 years of age, as well as mandatory counselling by a psychologist, psychiatrist or GP.[18]

Forensic gynaecological exams

Consent for forensic gynaecological examinations is of particular importance as it helps to permit a violated victim to re-establish her autonomy. The consent needs to be comprehensive and should cover general physical examination, abdominal examination, pelvic examination, the forensic and microbiological sampling from the genital organs and the use of any photography, including the release of data to approved recipients. Consent for photo documentation must be obtained.[19] Valid consent reflects a legal and moral principle whereby the victim has the right to decide what is appropriate for them. This includes the right to accept or decline a forensic examination and also to change that decision.[20]

Electronic consent documentation

An electronic signature is not viewed to be as secure as a physical signature because, as an image, it can be copied and used by another individual.[21] It is also seen as a less-ideal method for signing documents as it is more difficult to prove the intent of the person to sign. The practitioner needs to

be able to:
1. show that one can identify the person signing and be able to indicate that they knew and agreed to the document or the information they were signing; and
2. show that the method used to attach/affix signature was reliable. In other words, you need to be able to establish that the method of electronic signature was reliable, kept secure and was appropriate to be used for that type of document.

Digital signatures, on the other hand, are seen as a more advanced method of signing and have a higher level of integrity. They are seen essentially as an electronic fingerprint; a coded message that is unique to the document and the signer. Digital signatures ensure the authenticity of the signer. They are more widely accepted and a signer cannot later deny they signed after their digital signature is affixed. These consent formats are increasing in frequency, but for the time being a hard copy of the written consent should be retained for use when electronic signatures are not acceptable.

Consent by illiterate patients

It is permissible and valid for an illiterate patient to sign a consent form using a mark such as 'X' and the witnessing to such a consent needs to be detailed. The witness must be able to testify as to the validity of the signature. Similarly, patients without language skills or patients who are hearing or vision impaired are potentially capable of giving valid consent; however, the appropriate communication methods or support must be employed and documented in the patient's medical record. The use of family interpreters is not ideal because of potential conflicts of interest and may be open to later challenge.

Proxy consent

A proxy consent is based on the power of attorney (POA) where, for example, the right of an incompetent patient to consent to treatment is delegated to another adult. About one per cent of people aged 60–64 years and 12 per cent of patients aged 80–84 display signs of dementia, so alternative decision makers for those people are invaluable. The ACT, NSW, Qld, SA and Tas have enacted legislation that allows patients to appoint attorneys with explicit powers to be involved in their medical treatment either to consent to or refuse medical treatment on their behalf. WA may follow. A POA refers to the 'unilateral grant of authority by a donor for someone else to act on their behalf'. The POA may be general or enduring. The enduring POA continues after the principal has lost mental capacity.

Concluding remarks

When procedures go wrong and litigation follows, the issue of consent looms large in the minds of lawyers. Obtaining valid consent should not be motivated by a defensive mentality, but as an essential part of the therapeutic process. It is simply 'good medicine'.

Acknowledgements

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To treat or not to treat: does Gillick competence answer the question?

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It was a 1980 UK National Health Service (NHS) circular providing guidance to practitioners offering contraceptive prescribing advice to those under the age of 16 years that outraged Victoria Gillick. It stated:

> It is … widely accepted that consultations between doctors and patients are confidential, and the Department recognises the importance which doctors and patients attach to this principle. To abandon this principle for children under 16 might cause some not to seek professional advice at all. They could then be exposed to the immediate risks of pregnancy and of sexually-transmitted disease, as well as other long-term physical, psychological and emotional consequences which are equally a threat to stable family life… The Department realises that in such exceptional cases the nature of any counselling must be a matter for the doctor or other professional worker concerned and that the decision whether or not to prescribe contraception must be for the clinical judgment of a doctor.[1]

At that time, consent to medical procedures, including family planning advice and treatment, could only be given from the age of 16 years.[2]

In January 1981, Gillick wrote to the local health authority, requesting, 'written assurance that in no circumstances whatsoever will any of my daughters be given contraceptive or abortion treatment while they are under 16 in any of the family planning clinics under your control, without my prior knowledge, and irrefutable evidence of my consent. Also, should any of them seek advice in them, can I have your assurance that I would be automatically contacted in the interests of my children's safety and welfare? If you are in any doubt about giving me such assurances, can I please ask you to seek legal medical advice.'[3]

Victoria Gillick received a reply which stated that doctors would rely on clinical judgment. Her incensed response clearly stipulated that she 'formally forbid' any medical staff to give contraceptive or abortion advice or treatment to her daughters while they were under 16 years of age without her consent. Gillick's demands were not met and, subsequently, she commenced legal proceedings.

Her initial application to the High Court in 1983 was rejected. In his judgment, Lord Fraser respectfully noted that Mrs Gillick, a Roman Catholic, had a 'normal and happy' relationship with her ten children, including five daughters under the age of 16. He acknowledged that she was not motivated by an issue with her own children and that there was no 'likelihood of any of the daughters seeking contraceptive advice or treatment without the consent of their mother.'[4]

This decision prompted her to exclaim 'God Almighty… The judge doesn't realise there are a large number of doctors happily encouraging children to be promiscuous.'[5]

Her tenacity was rewarded with a successful Appeal Court ruling the following year, which stipulated contraception should not be given to girls under the age of 16 years without parental consent. However, the Health Authority appealed to the House of Lords in 1985. Lord Scarman concluded that 'as a matter of law the parental right to determine whether or not their minor child below the age of 16 will have medical treatment terminates if and when the child achieves sufficient understanding and intelligence to understand fully what is proposed.'

Therein, Lord Fraser described five criteria, that specifically addressed the dilemma of providing contraceptive advice to girls without the knowledge of their parents:

1. a minor should understand the doctor's advice;
2. the minor cannot be persuaded to inform her parents that she is seeking contraceptive advice;
3. she was likely to have sexual intercourse even if treatment were not offered;
4. unless she received contraceptive

advice, her physical and/or mental health would suffer; and
5. her best interest required treatment or advice without parental consent.

The Law Lords thus instituted a 'capacity criterion' for mature minors, replacing the status criterion of age 16 as the legal standard of consent.

Importantly, the Law Lords established a legal distinction between *consent for* and *refusal of* treatment by a minor. They concurred that the healthcare practitioner 'has recourse to the law, and in these cases the court decides whether or not this decision should be respected'.[4]

Australian law

The High Court of Australia has upheld the right of mature minors to consent to medical treatment in line with the UK Gillick decision, including when there is a conflict with the wishes of the parents. Table 1 summarises some important Australian case law decisions regarding consent of mature minors.

Some Australian states have impacted on the case law by enacting statutes that attempt to restrict some surgical procedures on young persons under 18 years. Specifically, Queensland has enacted laws to prohibit solariums and cosmetic procedures (presumably including gynaecological) on children, except when it is in their 'best interests'.[6] The law attempts to reconcile the competing issues of the child's vulnerability, respect for parental consent and a mature minor's autonomy.[7]

Australian courts, in line with the development of the Gillick test by the British Law Lords, have been reluctant to give mature minors the right to refuse necessary medical treatment. For example, in the management of diabetes,[8] therapy for self harm[9] and blood transfusions for Jehovah's Witnesses.[10]

The most recent controversy in the application of Gillick competence in

Table 1. Recent relevant Australian case law.

Case	Summary	Significance
Establishing Gillick competence in Australia 'Marion's Case'[11]	A 14-year-old intellectually disabled girl whose parents and doctors sought a court order for her to have a hysterectomy and oophorectomy to prevent pregnancy and menstruation, believed to be causing behavioural and psychological disturbance.	1. The Court was required to decide who makes the decision in such cases – the parents, the minor or a court authority. In summary, parents do not have the right to consent to sterilisation of their child as it is not a therapy thought to be in the best interests of the child. It is deemed to be a 'special medical procedure'. 2. Gillick competence upheld. The High Court stated that there is a sliding scale of decreasing parental control in a maturing child, regardless of intellectual disability.
Refusal of treatment X v The Sydney Children's Hospitals Network[12]	A 17-year-old of Jehovah's Witness faith with Hodgkin's disease had severe anaemia post chemotherapy. His doctors claimed that he had an 80 per cent chance of dying from the anaemia if no blood transfusion/ platelets were given. The hospital sought a court order permitting medical treatment, including sedation for administration thereof.	The Court held that while refusal to consent for mature minors was important, it did not prevent a Court from authorising medical treatment where the best interests of the child or young person require it.
Gender dysphoria Re Jamie[15]	Jamie (born male) had identified as female since age 2 years. At age 10, her pubescent development was of a 14-year-old male and, since she lived exclusively as a girl, she developed severe anxiety. Jamie sought, through her parents, Court approval for commencement of Stage 1 puberty-suppressing medication (Zoladex), which is reversible, and Stage 2 administration of hormone treatment (potentially irreversible).	The Family Court made a distinction between the stages of gender dysphoria treatment. • Stage 1: parents can lawfully consent for a child. • Stage 2: requires court authorisation, unless the child is Gillick competent. Furthermore, Gillick competence regarding Stage 2 treatment must be determined by the Court, even if the parents and treating clinicians agree.
Termination of pregnancy (TOP) of a 12 year old in Queensland Central Queensland Hospital and Health Service v Q[13]	A 12-year-old girl with complex social and psychological issues requested a TOP which was upheld by multiple health professionals (including two obstetricians) and her mother. The hospital requested a Court authorisation for protection from a criminal claim of trespass or illegal TOP. The Supreme Court granted permission for the TOP.	1. The Court commented: • It is appropriate that decisions about terminating the pregnancies of 12-year-olds should be referred to the Supreme Court. A decision to terminate a pregnancy is one procedure where the parent's consent is arguably not sufficient. • Gillick competence was not achieved as the child was unable to make an 'informed decision' since the consequences of the alternative choice, not terminating, were not fully apparent to her. 2. The criminal code of the Queensland abortion laws has been criticised as necessarily complicating the management of these children, causing potential harm.[14]

Australian law involves cases of gender dysphoria. Who has the authority to consent to potentially irreversible Stage 2 treatment? In Re Jamie (No 2)[15] the Full Family Court held that a transgender young person could undergo Stage 1 puberty suppression without requiring court approval. This has been viewed as a positive step in depathologising gender dysphoria and relieving families of the burden of expensive legal proceedings.[16] Additionally, potentially irreversible Stage 2 treatment with oestrogen or testosterone could be given to a Gillick competent minor without the need for court approval. That is, the court's only role is as a 'safeguard' for determining Gillick competence.

Policy and guidelines

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) supports the legal concept of the mature minor. RANZCOG acknowledges that in situations where a child is 'sufficiently intelligent' and 'sufficiently comprehends' the nature and possible outcomes of the proposed treatment, that consent may be given without parental input.[17] Indeed, this must take into consideration 'the young person's cognitive ability and their emotional understanding of a situation; their capacity to weigh up options and their consequences (both positive and negative); their ability to express their wishes; their capacity to make decisions in other areas.'[17] Nevertheless, RANZCOG does suggest that, especially in the setting of major diagnostic and therapeutic medical care, consideration should be given to the consent of a parent or guardian as the 'safest option'. In situations where this is not possible, a second opinion from either another suitably qualified medical practitioner or a medical defence organisation should be obtained.

Although Royal College of Obstetricians and Gynaecologists (RCOG) Guidelines state that each case must be individualised, RCOG too recognises that mature minors may consent independently, should they be deemed Gillick or Fraser competent.[18] It references the British Medical Association and the Law Society (England and Wales) by recommending the following criteria are used when assessing the capacity of a minor:[19]

- the ability to understand that there is a choice and that choices have consequences;
- a willingness and the ability to make a choice (including the option of choosing that someone else makes treatment decisions);
- an understanding of the nature and purpose of the proposed procedure;
- an understanding of the proposed procedures, risks and adverse effects;
- an understanding of the alternatives to the proposed procedure and the risks attached to them, and the consequences of no treatment; and
- the freedom from pressure.

Importantly, special attention is drawn to refusal of treatment. Indeed, it is highlighted that minors may not have the same legal rights to withhold consent, such that refusal of treatment may be overridden by parental consent or the courts.

The National Institute for Health and Care Excellence (NICE) also endorses the Fraser guidelines.[20] It specifically outlines a gold standard of care for the provision of contraceptive services. It proposes that both written and verbal information on all types of contraception be made conveniently available at all times. Furthermore, it suggests that contraception will be optimally used if an individual has the ability to choose the method most suitable for her/his particular needs and lifestyle. Notably, this also applies to 'everyone under age 16 who is competent to consent to contraceptive treatment.'[21]

Conclusion

Victoria Gillick set in motion a series of legal proceedings addressing the issue of consent by minors that continues to guide us today. The House of Lords introduced the notion of the 'mature minor', enabling children under the age of 16 to consent should they be deemed competent to do so. It is clear that the ability to consent means more than simply understanding the general nature of the treatment. Evidently, one must demonstrate an ability to understand the broader consequences of the decision, and the capacity to balance the risks and benefits of the proposed treatment. It seems widely accepted that we retain Gillick competence as the principle with which to judge capacity in children. The Fraser guidelines should continue to be used as they were initially described, recognising the importance of the Gillick test for guidance of children receiving contraceptive advice.[21]

There are likely to be further developments of the Gillick test in the law with regards to refusal of treatment and gender dysphoria.

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Consent for clinical research trials

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Clinical research is a crucial partner to best clinical practice. It can include the study of disease prevention and causation, diagnostic tests, new or different treatments, and the prognosis and outcomes of different conditions.[1] Clinical trials are a specific form of research designed to find out the effects of an intervention, where the intervention may be a drug, a surgical or diagnostic procedure or a device.[1] When deciding if a treatment or intervention is beneficial or otherwise (whether it improves outcomes), appropriate testing of the intervention will often involve a clinical trial, in a randomised or cohort type of methodology.

Research methods have been developed to minimise bias in clinical trials; these include randomisation and 'blinding' or 'masking' of participants and researchers to the identity of agents or procedures being compared. The very use of such methods implies ethical issues that must be addressed with participants. Human research is unique in that human beings have the capacity and right to make decisions for themselves. In clinical research, this brings about the requirement for informed consent. This requirement has the following conditions: consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation.

All principles that guide our conduct when undertaking clinical trials have their origin in the World Medical Association's Declaration of Helsinki.[2] In the Australian research environment, the National Health and Medical Research Council plays a role in providing guidance and advice to researchers as well as those that are involved in their approval and conduct, such as ethics committees.[3]

From the perspective of the team

From the perspective of the research team, clinical research of any type is time consuming, resource intensive and expensive. Many processes need to occur before a researcher even has an opportunity to discuss their study with a potential participant. All clinical research trials involving an intervention ideally commence with a clinical situation in which, after a thorough search of the literature, there remains insufficient evidence to inform the best course of treatment. By the time a clinical research trial is recruiting participants, the trial protocol has been reviewed by a human research ethics committee that will include a scientific review, if this has not already been done. If the particular trial has funding, it will also have been peer reviewed for scientific merit and methodological rigour by the funding body. Clinical trials running within publicly funded institutions also undergo a governance review, which ensures that the institution can support the research trial and that all costs, including monetary and time, have been accounted for and will not burden the institution.

Facilitating consent

In our experience, we have found that it is essential to engage with clinical staff working in the setting in which recruitment will occur. It is important that a research culture exists and that clinical staff have been presented the trial protocol, including the rationale and procedures. Research is core business within public teaching hospitals and for this culture to exist, clinical staff should be aware of the process that has happened before recruitment commences. That is, research gap demonstrated, lack of evidence for the clinical situation, scientific and ethical approval – and importantly, the rights of potential participants to have access to a treatment that may be beneficial and would otherwise be unavailable.

Research staff should work within all clinical settings with great sensitivity to priority of clinical care of potential participants. Clinical staff within public hospitals are working in stressed environments that are often under-resourced. Clinical care is always a priority and research should fit in around the clinical priorities. Ideally, participation in a trial should be presented as part of clinical care, with the clinician discussing the management plan and the study with the patient. If relevant, the clinician should explain that best treatment for the condition is currently uncertain, and a trial is available that may or may not benefit the participant, but will assist clinicians to gather high-quality evidence that will benefit other patients in the future.

Any processes that are put in place to assist recruitment to clinical trials should consider the clinical scenario (that is, the busy outpatient department, antenatal clinic, elective theatre or delivery suite) and aim to enhance the experience of the woman as the potential participant. Despite researchers considering different tools to increase the understanding of participants, it is apparent that a study team member taking time to talk individually to potential participants is the best approach.[4]

Barriers to obtaining consent

For a clinical trial to be considered by a woman/participant, it should ideally be introduced by a clinician, either a midwife or obstetrician who is supportive of the research, who is able to answer

any initial questions the woman may have. As researchers, we often find that participants have been actively discouraged to be involved with research, as a direct or indirect result of negative views expressed by the clinicians providing their clinical care. Another significant barrier for gaining consent and participation in trials occurs when clinicians offer the experimental treatment outside of the trial. This hinders both opportunity to accrue participants and evidence for best clinical care.

Practical aspects of consent

There are many ethical guidelines to obtaining consent.[1] For a detailed assessment and explanation of risks and benefits as they pertain to consent, we refer the reader to the NHMRC National Statement on Ethical Conduct in Human Research.[4] Here we provide what we deem, in our experience of working in perinatal clinical trials, to be some of the important points to consider. Trial information should be provided in verbal and written forms, and written informed consent is then obtained from the participant. When counselling, it is important to consider the points listed in Box 1.

It is always important to allow sufficient time (when possible) for the woman to: consider participation in the study; ask questions; discuss with partner, family, other support person or healthcare provider; and then be able to answer questions. Documentation in medical records should indicate that trial information has been provided and whether the woman consented or declined.

Special considerations

There are several unique aspects and ethical considerations when obtaining informed consent for perinatal trials, our area of interest and experience. Situations such as when women are in labour, expected to deliver preterm, or their baby is expected to require intensive care or be otherwise unwell at birth, can prove difficult for obtaining consent. At these times, women and their families are often anxious and overwhelmed and there will be varied essential clinical care to be given. The wellbeing of the woman and baby should always take precedence, but it is possible to provide information about clinical trials in a sensitive and appropriate way. There may be limited time to obtain consent if birth is imminent and, if consent is obtained in this type of situation, it is worthwhile seeing the woman a day or two after the birth to discuss the trial in more detail.

Antenatal interventions, especially drug trials, bring another aspect of complexity to consent. Women are often hesitant to expose the fetus to drugs unless absolutely necessary and don't want their baby to be a 'guinea pig'. The issue of drug trials in pregnancy is a complex one, highlighted by a recent article by Scaffidi and colleagues,[6] which was the subject of an interesting Twitter-based discussion on the same subject. The authors report that 0.32 per cent of all active registered studies on clinical trials registers were perinatal drug trials.[6] It is likely that this is multifactorial in cause, but in our experience, the degree of administration and frustration associated with approving perinatal drug trials, even to the point of being able to approach a participant for consent, is inversely proportional to the aforementioned percentage.

In summary

The establishment and coordination of a clinical trial is an expensive, resource-intensive undertaking. The need to address a clinically important research question must be demonstrated, funding obtained, the necessary approvals sought and study materials and procedures developed. A research culture and a keen local investigator with the support of clinical staff are vital to the successful running of a trial. Whenever the clinical situation allows, potential participants deserve the opportunity to consider the study information and make the informed decision to take part in a trial that may benefit themselves or their baby. The importance of the support of clinicians who are willing and able to counsel potential participants and seek informed consent cannot be underestimated. The successful completion of a clinical trial within a reasonable timeframe can provide evidence that changes clinical practice, benefits patients and may save valuable health resources.

Box 1. Points to consider when obtaining consent for clinical trials

- The aims of the study
- What we know and don't know about the clinical condition
- Who is eligible for the study
- Whether the study is comparing a new treatment with control or new treatment with current standard care
- How and why random allocation to one of the two groups will occur
- Why there is blinding to treatment group and reasons/advantages of this
- Comparison of outcomes, what outcomes we are interested in and why
- What participation involves for the participant
- What is additional to standard care
- Participant may or may not benefit
- Potential risks and benefits
- Participation is voluntary, able to withdraw at any time without effect on care received
- Privacy and confidentiality
- Research team to have access to medical records for relevant data collection
- Collection of contact details for participant and other supports
- Respect for culture
- Consider those with low literacy/educational background – use appropriate language
- Is an interpreter required? Can partner/other family assist?
- Are you comfortable the patient understands what is involved to participate; is it 'informed' consent?

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‘Hey baby, what’s your number?’

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A new kind of patient is emerging (or has emerged, depending on your practice) – an informed, internet-savvy, choosy patient, born out of the union of advanced technology and overriding consumerism. More than ever before, health-related information is available to this patient. Good and bad information is a few clicks away; published by thousands, accessed by millions, and policed by few.

At some point in his or her health trajectory, this patient will likely require a surgical intervention. Woe to the surgeon hit with the onslaught of Googled patient stories, You-Tubed surgeon repertoires (because who doesn’t put their best stuff online – look at me, Mum!) and some sort of, mostly irrelevant, checklist created by a Facebook patient-advocacy group. After wading through this pool of internet hullabaloo, the surgeon will finally recommend the appropriate intervention, only to be met with ‘and how many of these have you done?’

When I was a trainee, a mentor gave me some interesting advice in regards to this question: ‘Say “Oh, I’ve done a number of these procedures” because, even zero is a number.’ While this answer is funny, albeit purposefully misleading, it hints at a common concern of physicians. ‘Do I have to answer this question? I’m actually offended it was even asked.’ My inner, white-coat-shrouded, hierarchy-abiding, Hippocratic oath-spouting, super surgeon scoffs at the audacity of a patient to even think to ask such a question. (Don’t act surprised, you know you have one hiding inside you, too.) We have entered an era of consumer-driven medicine, as dangerous as that is, where quality drives reimbursement, even privileges. Dare I say, that may be a good thing. So is it so wrong to include surgeon volume in informed consent? How do we go about doing that?

Point: Patients should not have access to surgeon numbers, nor should they ask.

Recently, I went on a cruise to the Bahamas with my family. This trip required two flights on commercial airliners, two bus rides, and a voyage on a very large boat. Not once did I think to ask the pilots, the bus drivers, nor the ship’s captain their crash records or number of flights/bus trips/voyages. Why? Because I have trust in those industries; in the training of those individuals, the systems that oversee them and the equipment they operate. And more importantly, I don’t want to know. I like being ignorantly happy. Additionally, I cannot imagine the amount of research it would take to fully investigate each part of my journey to identify potential risk. It wouldn’t stop at the pilot/bus driver/captain, but would include all the maintenance workers for each of those vehicles, air traffic control, the coast guard, and on and on and on. No amount of information could completely allay my fears. And I’m pretty sure no one is going to give me all the information anyway. So, as far as an individual surgeon is concerned, how helpful is one number? Any surgeon will tell you, the success of a surgery is dependent on many more variables than just the surgeon. The guy in the basement processing your instruments can ruin your whole day.

Let’s just say, for argument’s sake, that an open display of surgeon-volume becomes a natural part of consent. Where does it stop? What’s next? Complication rate? Readmission rate? Number of near-misses? By complying with consumer demand, you increase consumer desire. And, the consumer desire is to always know more and control more. It’s called demand for a reason. Thus results an unintended transfer of power. Kind of a dirty word to use in medicine, but it is power nonetheless. In most settings, power and knowledge are proportional – as they should be. Those with the most knowledge also have the power. A good example is a police force. The person with the power to put me in jail should also have the most knowledge about my rights and the law I have broken. If a police officer had less knowledge than the citizen, but still the power to incarcerate, chaos would ensue. The same would happen in medicine. We would become retail sales people as opposed to the guardians of medical care, complying with the wishes of under-informed patients, regardless of potential health risks to the patient and the population.

Ultimately, the sacrificial lamb in this situation is the trainee. How does a trainee or recent graduate answer the question of case volume? A downstream effect of publicly available surgeon-volume is a shift of surgical cases toward seasoned surgeons and away from trainees and younger surgeons, with disastrous consequences for the future of medicine.

Counterpoint: Patients should have access to surgeon volume and should be encouraged to ask.

Selfishly, this is the reason I have a job. I am a minimally invasive gynecologic surgeon. My training itself is designed to give me a special focus and high numbers in certain types of surgical procedures. And I like that the literature endorses better outcomes, lower cost and higher patient satisfaction with high-volume surgeons. If I were the patient, that is what I would want. Wouldn't we all? Is it fair for us to expect a wall of protection as surgeons, while we secretly dig a tunnel under that wall when we become patients? Additionally, when patients ask for information, this adds another layer of accountability, and accountability, whether we like it or not, is a good thing. If we don't police ourselves, someone else will. The tide of patient demand will not stop, and higher authorities, with dollars on the line, will capitulate. If we don't offer up the information that is requested, someone else will. I would much prefer it come from me than a page on an internet site.

Final point

Really, we should not be asking ourselves 'how do we answer this question', but 'why are patients asking in the first place?' Patients ask this question because they are afraid, and they want the best-possible outcome. Who can blame them? I am frequently in awe of patients, actually. They willingly lay themselves down on my table; naked, cold, surrounded by strangers, with needles in their arms and choose to become unconscious, while I move their bodies and stick them with sharp instruments. They understand that a slip of the knife could have disastrous consequences. Yet, they trust me. That is an amazing and heavy responsibility. I have a duty to put them at ease. If that means giving them an account of my experience, I will. But in addition to your volume, patients should have a grasp of your training, your years spent working with a mentor and the other qualifications you have that allow you to stand in that room, obtaining informed consent. If they still have concerns, offer to scrub this case with a senior partner, someone they feel comfortable with assisting you. When patients question our credentials, this comes more from a fear of loss of control than an attack on our abilities. Stand up for yourself, recite your qualifications, be confident in your skills, and use that knowledge to create confidence in your patients, too.

Medical students seeking consent

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A significant aspect of the art of practising medicine is the ability to obtain genuine informed consent. Medical students learn in an apprenticeship model and how they observe their medical tutors obtaining a patient's consent will greatly affect their future practice.

Obtaining consent

Although medical students are rightfully members of the healthcare team, it is important to understand that being given the opportunity to interview, examine and to possibly participate in a patient's treatment is a privilege and the patient may withdraw his or her consent at any time.

The primary responsibility for ensuring consent has been obtained lies with the medical practitioner, not the student. The consenting process should occur in an environment where the patient feels no pressure to provide consent and must occur before the student is involved in the patient's management. As circumstances in the patient's medical condition may change over time, the student should be aware that consent needs to be obtained for each instance of care.

It is quite appropriate to inform the patient that the medical student is a member of the healthcare team, but it is inappropriate to introduce the student as a junior colleague or young doctor. These euphemistic terms are misleading and may indicate to the patient that the student could possibly have some input into the decision-making process relating to his or her treatment.

The student should understand that an ethical consenting process not only provides protection for our patients, but also for the healthcare professionals involved with their care.

Types of informed consent

There are several types of informed consent, as shown in the box below:

Verbal consent, which can be general or specific.
Written consent into the patient's notes, or a consent that is signed by the patient.
Consent for educational purposes only.
Consent for the student to be involved in part of the patient's management.

In general, the nature of the consent will depend on the amount of involvement from the student and the potential risks to the patient. Therefore, verbal consent should be limited to history-taking, observation, non-sensitive examinations and basic procedures conducted under supervision.

Specific verbal consent should be obtained for procedures such as giving injections, intravenous cannulation or suturing. If the procedure would normally be recorded in the clinical notes, the consent should also be recorded. It is important that students do not undertake procedures on patients unless they have obtained the appropriate knowledge and skills training related to the procedure. All procedures should be supervised until the tutor is satisfied that the student is competent to perform the procedure unsupervised.

The difference between consent when a student undertakes an examination primarily for educational purposes, as compared to an examination which the student performs as part of the patient's management, needs to be appreciated. For example, if a student in the operating theatre setting is directed by the surgeon to assist or perform an examination that directly relates to the patient's management, as long as the patient is aware that a student will be working with the surgeon, verbal consent is adequate. However, if an examination or procedure is to be performed by a student solely for educational purposes, prior written consent must be obtained. This especially applies for intimate physical examinations such as vaginal, rectal or breast, when the examination is performed under anaesthetic.

Clinical settings

In broad terms, the clinical settings for obtaining consent fall into the two categories of inpatient and outpatient. Inpatient settings include emergency departments, intensive care units, operating theatres, birth suites, neonatal units, adult and paediatric wards and mental health units. Outpatient settings in the obstetrics and gynaecology area include clinician's rooms or outpatient departments in hospitals. Each of these areas has unique requirements for consent.

In each of these settings, students should be readily identified as a medical student and a name badge indicating their status should be worn during times of patient contact.

In a clinician's room, signage and pamphlets indicating that the practice is involved in medical student education is helpful in explaining the presence of the student and in assisting with the consenting process.

In my practice, administrative staff inform the patient on arrival of the presence of the medical student and ask the patient if they are comfortable with the student being present for the interview and/or examination. If the patient consents to having the student present, the student will then introduce themselves to the patient in

the waiting room and again confirm that consent has been obtained for them to be present. When the patient enters for the consultation, I also confirm consent simply by verbally verifying that they have met my student and are happy for the student to be present. This process minimises the risk of the patient feeling pressure to give consent.

In the hospital environment, I have noted quite a variation in the protocols that students employ to obtain consent from the patient. At a minimum, a student should seek permission from an appropriate member of the patient's healthcare team before entering the patient's room to obtain their consent. They should always explain to the patient that they are a medical student, that there is no obligation to consent to the interview and/or examination, and that the patient can terminate the interview at any time.

The student should also have a low threshold for terminating the interview if the patient indicates any hesitancy regarding the interview and/or examination. The consent should be recorded in the patient's chart or the student's notes.

Areas of difficulty

Challenges arise in this process where the patient is temporarily or permanently unable to make informed consent. For example: neonates, minors, unconscious patients or patients with mental illness. There is also the category of patients that are not competent in the English language.

If possible in these circumstances, consent should be sought from their legal guardian, with the awareness that the person obtaining the consent should always address and respect culture, religion and language diversity. In some of these situations, student involvement may not be possible or may be restricted to observation alone.

A possible solution in such circumstances may be the inclusion of a statement in the admission form that indicates that medical student teaching is undertaken at this institution and that students may be involved in observation or patient procedures under supervision. The patient and or guardian can opt out at this time.

Confidentiality

As part of the consenting process, students should be made aware that they must respect the confidentiality of all patients and not discuss the clinical details of a patient, even in a de-identified manner, outside the clinical setting. This includes public places within the institution such as lifts, corridors and dining areas.

Conclusion

It has been my experience that the vast majority of patients are only too willing and happy to allow medical students to be involved in their care. It is therefore imperative that this privilege is not abused. Appropriate informed consent must be obtained for the student's involvement, and our students must also understand the importance of this process.

Further reading

National Statement on Ethical Conduct in Human Research.
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End-of-life care

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Decisions to withhold or withdraw life-sustaining treatment are ethically, professionally and legally complex, especially when the patient has lost decision-making capacity.

This article discusses some of the legal principles associated with the provision of end-of-life care and outlines the consent process that underpins these decisions.

Legal principles

Doctors are not under a legal duty to provide 'futile' care, even if this is requested by the patient and/or their family. In end-of-life care, medically futile treatment can be considered to be treatment that gives no, or an extremely small, chance of meaningful prolongation of survival and, at best, can only briefly delay the inevitable death of the patient.[1] That is, where the treatment is of no medical benefit to the patient, or the burdens of the therapy are out of all proportion to any potential benefits. Futile treatment may include life-sustaining treatment. The determination of futility must be appropriately made and, ideally, there should be consensus with the patient and/or their substitute decision-maker with respect to the assessment of futility. A patient, their family or substitute decision-maker can legally challenge a decision not to provide futile treatment.[2]

It is a crime to deliberately take another person's life or to assist another person to commit suicide. A doctor should never provide treatment with the intention to end a patient's life, or to assist the patient in doing so. However, a doctor can administer medication to a patient with the sole intention of relieving pain and suffering ('good effect'), even though this may hasten their death ('bad effect'). This is commonly referred to as the 'doctrine of double effect', and is an exception to the general rule that taking active steps to end a person's life is unlawful. In this situation, the administration of medication to the patient should not achieve the relief of pain by hastening their death, and the need to relieve the pain and suffering must be such that it outweighs the consequences of hastening death.

Capacity for treatment decisions

By law, all patients who are 18 years or over are assumed to have capacity to make decisions, but that presumption can be rebutted where the need and evidence arises. Generally, a person with capacity will be able to:

- understand the facts of the situation;
- understand the main choices available;
- weigh up those choices, including benefits and risks;
- make and communicate their decision; and
- understand the ramifications of the decision.

An adult patient who has capacity can refuse medical treatment, even if that refusal will result in their death.[3]

Advance care directives

Life-sustaining medical treatment can also be refused through an advance care directive (ACD). An ACD is generally a written document, intended to apply to future periods of impaired decision-making capacity, which provides a legal means for an adult to record preferences for future health and personal care and/or to appoint and instruct a substitute decision-maker.[4] ACDs are not clinical care or treatment plans, but clinical care and treatment plans can and should be informed by ACDs.

The common law recognises, as part of the right to self-determination, that an individual can complete an ACD that will bind a health practitioner who is treating that person, even if the directive refuses life-sustaining treatment. A 2009 NSW Supreme Court judgment confirmed that if an ACD is made by a competent adult, is clear and unambiguous, and extends to the situation at hand, it must be respected.[5]

Legislation governing ACDs has been enacted in every Australian state and territory, except NSW and Tasmania, although the legislation and the terms used for these directives varies from state to state and is subject to change.[6,7] In some states, the legislation also places limits on the

application of an ACD; for example, that it may only operate if the patient is suffering from a terminal illness or has no reasonable prospect of regaining capacity.

Lack of capacity for decision-making

As outlined above, where a patient lacks capacity to make their own decisions, priority must be given to a valid ACD, if this exists. In the absence of an ACD, consent should be obtained from a substitute decision-maker. Every state and territory has guardianship legislation which regulates, to varying degrees, medical treatment decisions for adult patients who lack decision-making capacity. The legislation outlines a hierarchy of decision-makers. This may include an enduring guardian who was appointed by the patient when they still had capacity, a spouse, other family member or unpaid carer. These substitute decision-makers must act in accordance with the patient's wishes (if known) or in the patient's best interests. Where there is no available substitute decision-maker, an application can be made to the relevant Guardianship Tribunal for the appointment of a guardian.

Decisions to withhold or withdraw life-sustaining medical treatment are complex and serious, especially in view of the gravity of the outcome. In some states and territories, the legal authority of a substitute decision-maker to decide to withhold or withdraw a patient's life-sustaining medical treatment is not clear. There are also differences in the definitions of life-sustaining treatment/measures. This is a complex area of the law and doctors should contact their medical defence organisation for advice in a particular case if they are uncertain how to proceed.

This article is provided by MDA National. They recommend that you contact your indemnity provider if you need specific advice in relation to your insurance policy.

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Postmortem sperm retrieval

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Postmortem or posthumous sperm retrieval (PMSR) involves the collection of sperm from a recently deceased male for the purpose of posthumous reproduction. Since 1980, advances in assisted reproductive technology (ART), particularly the high success rates associated with intracytoplasmic sperm injection (ICSI), have made PMSR increasingly feasible as a way to allow someone to conceive a child despite the death of the prospective biological father. While the medical procedure to retrieve sperm (from the vas deferens, epididymis or testis itself) is straightforward, the ethical and legal issues associated with retrieval and use are complex.[1] This article looks at the ethical issues associated with the use of sperm following a man's death, issues that have been described as among 'the most challenging, difficult, and sensitive … in the field of medicine'.[2]

Explicit written consent prior to death is the test required in most Western legal jurisdictions that allow, or at least don't prohibit, the postmortem collection of sperm and its subsequent use in artificial reproduction, including the UK, New Zealand and several Australian states. Such a test is widely seen as the appropriate way to show respect for the autonomy of the deceased. Note that consent here is understood as properly informed consent, and so includes competency, disclosure, understanding and voluntariness.[3] Men who consent are supposed to understand what PMSR-based conception involves, to have thought about its impact on their partner and the child, and to have decided freely that this is a course of action they want.

For some jurisdictions, such a stringent form of consent is still not enough to permit PMSR and posthumous conception. PMSR is illegal, for example, in France, Germany, Sweden and Canada. But should the test of explicit consent even be considered a requirement for such procedures? Much of the recent debate on the topic of the appropriate kind of consent focuses on the fact that men who die suddenly (in accidents, for example) are not likely to have thought about giving explicit consent, even though they may well have wanted their partners to have their child under these circumstances. This has led a number of ethicists to propose another model of consent: implied, inferred or hypothetical consent, here understood as the idea that it is enough that the person concerned would, on the balance of probabilities, have consented to the course of action in question – in this case, that the deceased would have consented to having sperm retrieved and used for conception had he been presented with the relevant facts pre-mortem. The Cornell guidelines used by several New York hospitals require either explicit or implied consent, calling this 'presumed' consent.[4] Israel is sometimes said to use a system of implied consent when considering PMSR, but in fact, Israel requires little more than evidence of the desire for fatherhood on the part of the deceased.

It is important to stress that evidence for implied consent on the part of the deceased requires evidence that the deceased would have consented to certain procedures happening after his death, not merely that he might have consented. Given the nature of PMSR, however, the evidence for this is often problematic. Even the fact that the couple were known to be considering IVF, for example, tells us nothing on its own about the man's feelings about PMSR and posthumous fatherhood. What if the partner states that the deceased had indicated a preference for PMSR were he to die, with family members backing up her testimony? The problem with this kind of testimony is that it is not only subject to confirmation bias, but the man's partner as well as other family members have an obvious conflict of interest – they have a motivation to hide the truth, or put a certain spin on things the deceased might have said.[2,5] Not surprisingly, many ethicists think that the difficulty of verifying implied consent leaves a system of explicit consent more clearly aligned with the ideal of respect for personal autonomy than a system of implied consent.

How does all this compare to the ethics of consent in the case of organ donation following death? There are both similarities and differences. In the case of posthumous organ donation, explicit consent seems again to be the consent regime that best supports the ideal of personal autonomy; even though the kind of opt-in mechanism typically used in the case of organ donation (ticking a box on a driver's license, say) scarcely meets the conditions of informed consent, which in turn may help to explain why in so many jurisdictions the next of kin have the ability to override the deceased's consent. By the nature of the case, no such overriding can take place in the case of

PMSR and posthumous conception, since the wishes of the deceased man's partner, not the deceased alone, play an integral role in determining whether the procedures should go ahead.

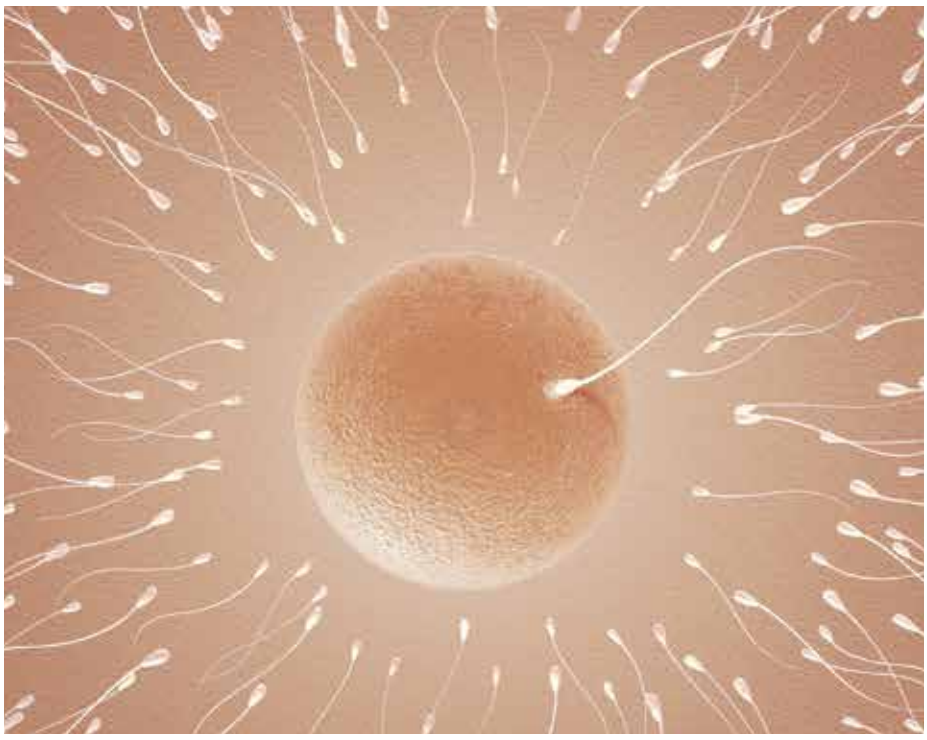
In the case of posthumous organ donation, the fact that a regime of explicit consent often goes hand-in-hand with a low rate of organ donation has been an important driver behind arguments for a very different notion of consent: presumed consent, implemented by an opt-out system, where it is 'presumed' that a person has given consent unless he or she explicitly indicates that they decline consent. In the case of PMSR the debate has mostly involved the choice between explicit and implied consent, but there are now signs that this is changing. Recent papers, such as Tremellen et al[6] and Young,[7] argue that a strong case can also be made for a regime of presumed consent in the case of PMSR and posthumous conception, since there are few significant moral differences between the case of posthumous organ procurement for the purpose of transplantation and posthumous sperm procurement for the purpose of posthumous artificial conception. In particular, Tremellen et al argue that PMSR and conception may well be in the best interests of the deceased's partner, and that where there is a tension between an individual's self-interest and a demand of morality, such as consideration for others, the individual has a moral duty to follow this demand if it comes at little cost to the individual (the so-called duty of 'easy rescue').[8] Furthermore, they argue that there is good statistical evidence to suggest that men would want posthumous conception if their partners wanted it. Their conclusion is that the best way to accommodate these considerations is a system in which men are presumed to have consented to PMSR and conception unless they expressly choose to opt out.

The concern about this approach is whether a system of presumed consent takes sufficient account of personal autonomy and the interests of the deceased.[9] Tremellen et al argue that the interests of the living trump the interests of the deceased because 'the dead person no longer exists, so at that time cannot have interests or be autonomous'. This reasoning is problematic, however, as it implies that, for example, instantaneous killings do no harm since at no point of their victims' existence do the killings affect the interests of their victims. The condition also cuts across conventional wisdom, both legal and moral, about signed deeds that concern events in which the signer has an interest, but will occur after the death of the person signing.

Tremellen et al also suggest that surveys on men's beliefs about posthumous conception suggest that men by and large would want posthumous conception if their partners wanted it. Unfortunately these surveys are poorly representative, since they involve men who have had their sperm frozen, as well as couples trying to conceive. A more representative US survey is reported by Hans,[10] which similarly supports a policy of presumed consent. But appealing to such surveys is problematic, for why should the preferences of the majority dictate a policy that will apply to all men, including those who would not approve of their partner's use of their sperm? (The fact that a policy of presumed consent allows men to opt out means little; as often happens with opt-out systems, even those with strong views may simply give no thought to the remote chance that they might be affected by the policy.)

Are there other arguments for a regime of presumed consent for PMSR? It could be argued that organs able to be transplanted become a mere resource once their possessor has died. Can sperm be considered in the same way? On such a pure resource model, a man's viable sperm is a pure genetic resource, usable by his partner, and benefiting both man and partner if he is alive and a child is produced, but his partner alone if he is deceased and the sperm is released to her for purposes of artificial conception. As a pure genetic resource, the sperm is something the deceased has no interests in, apart from it being part of his body. This limits his autonomy, since none of these things can be used to his benefit after death (and not simply because there is no 'him' to benefit). Any duties he has as a moral agent prior to death can only involve the way he might enable this resource to confer a benefit to others, especially to his partner since she is the one who can benefit most directly through artificial conception. This viewpoint lends itself to an opt-out scheme.

Compare the pure resource model with an alternative model that we might call the relational model. This, we think, is the model at play in the debate between the two 'standard' positions discussed earlier: explicit versus implied consent as a necessary condition on PMSR and PMSR-based conception. On the relational model, gametes, including sperm, are invested with a certain relationship potential: people care about their potential offspring, seeing them as their offspring, a relationship that is centred on them. For that reason, they don't consider sperm to be a pure genetic resource in which they can't sensibly be said to have interests after death. If the sperm are used to conceive a child, the child is theirs and they have a vested interest in what happens to that child, even if they are not around to help rear the child. That is precisely why they might refuse to give explicit consent to having their sperm used for the purpose of artificial conception. That is also why there is no clear



PMSR provides the opportunity of conception following death. © Tim Bird/Shutterstock.com

duty of 'easy rescue': even if a man has a prima facie duty to help his partner achieve happiness through helping her conceive a child, since the child will also be his child it is morally appropriate for him to make sure his interests are protected. This also explains the importance of agent autonomy and the quality of the consent.

Many people, we suspect, would accept the pure resource model as the appropriate model in the case of posthumous organ donation, and this may explain why a policy of presumed consent for posthumous organ donation doesn't, by and large, strike people as morally outlandish. What about PMSR? Which model best captures the way men belonging to our culture think of sperm and its potential for use? The answer to this question will tell us which policy is likely to sell: important if one is designing healthcare policy and protocols around PMSR and PMSR-based conception. So far, the evidence favouring a pure resource model is far from clinching.

The conclusion we come to, then, is one of caution. So far, at least, the case for a presumed consent regime for PMSR and PMSR-based conception does not look as promising as it may be in the case of posthumous organ donation. Even an implied consent regime has clear problems; in particular, the epistemic problem of knowing what the deceased would have wanted. It is important that the debate continue, but as things stand, we think the morally safest option is a system of explicit consent or, at best, a system of implied consent with stringent demands on the level of evidence required.

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The implications of clinical images

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It is a common scenario for doctors in training. You see a patient with your consultant and there is an abnormal rash, ECG or snapshot of a CT scan that needs further exploration. You've suddenly got two choices in front of you. You can attempt to describe the anomaly to the specialist on the other line and try your absolute hardest to ignite your inner Shakespeare. Or, you can pull your ectopic brain out of your pocket, take a photo and send your digital Van Gogh directly to the specialist. I don't know about you, but my Latin just isn't that good. It is no surprise then that images are being taken on smartphones and sent to colleagues for further opinion every day, but what exactly are the broader implications of our current de facto practices? To understand how we've ended up where we are today, we need to look at information in healthcare at a broader level, specifically outlining issues of privacy, confidentiality and consent.

Privacy is quite a broad concept and there is no all-encompassing, singular definition of what privacy means. Roger Clarke defines privacy at the broadest level as, 'the interest that individuals have in sustaining a personal space, free from interference by other people and organisations'.[1] Privacy is not a static concept and has multiple subjective boundaries.[2] The degree to which these align enables a clearer definition of privacy for a given situation and problems arise when the expectations of privacy conflict with one another. For example, the Victorian government recently introduced laws to make vaccination compulsory for children to attend childcare or kindergarten.[3] With Victorian vaccination rates at 92 per cent, it is clear that the majority of Victorians are willing to forego some personal privacy of the body to protect their public health. However, a small minority continue to challenge the idea of vaccination. These conflicts in expectation of privacy are ultimately managed by the Australian legal system.

Privacy is also intertwined with the concepts of confidentiality and consent. If information is considered private, then there are expectations around how that data will be managed, including an expectation of security. Confidentiality is the idea that information communicated between parties will be kept in confidence.[4] Confidentiality is also relative, and broader interests may override the expected confidence. For example, medical practitioners are sometimes directed to break confidentiality if there is an overriding public interest, such as can be the case with specific dangerous infectious diseases.[5]

The provision of informed consent is discussed in privacy legislation. Informed consent is a voluntary choice or permission, made freely by an individual who has sufficient information available to understand the implications of their decision.[6] In obtaining this consent, an individual must be informed of how their data are to be used and shared, including instances in which these restrictions may be overridden through exemptions. Models for the sharing of healthcare information operate either by opt-in or opt-out mechanisms for consent, whereby patients must either provide informed consent to enter the system, or elect to exit the system after having already been added to it.

So what does all of this mean for the doctor in training and our troublesome rash? We all carry devices on our person with the ability to record high-definition photos, video and audio and yet we have no uniform, secure systems with which to transfer them to each other. When you use bedside media to deliver medical care, you're creating a new part of the medical record and there are rules and expectations around the management of this record, as we have touched upon. Let's say that you decide that media is necessary to deliver medical care to your patient. Does the patient understand what will be done and why it needs to be done? Has their consent been obtained and recorded properly? How will the images be stored? Do you have automatic backup services on your phone that might send that data to the other side of the world, outside of an Australian legal jurisdiction? What policies do your local hospitals or clinics have in place for these situations? How will you store the media in the record for the required amount of time? What will you do if the patient revokes consent? Suddenly, our rash doesn't seem like just a small problem anymore.

The reality is that storing electronic media in modern-day clinical records is a veritable nightmare of legislation, policy and procedure. It's so complicated and so variable that it is often easier to take the picture, send it off and just pretend it never existed. However, it did exist and will continue to exist in devices and storage outside of your control. The reality is far from ideal. Doctors can't wait for the system to evolve and catch up. They need to deliver the best care they can for their patients right now, and often that brings tenants of practice into conflict with each other.

In 2014, the Australian Medical Association (AMA) joined forces with the Medical

Indemnity Industry Association of Australia (MIIAA) to develop a clear guideline for clinical images and the use of personal mobile devices.[7] This guideline provides clear information on the responsibilities of doctors and medical students in dealing with clinical images. The guideline includes a single-page flowchart to inform decisions made at the bedside with regard to collection, use, disclosure, storage and security (see Figure 1). This body of work recognises the enormous complexity of clinical imagery and the benefits it can provide, and helps us to navigate these complicated waters.

The sad reality of modern medicine and modern technology is that the disparity between the two is a gulf that seemingly continues to expand. I can get off of a plane anywhere in Australia and my phone can instantly find the closest cinema, find the most popular movie and buy me two tickets automatically charged to my credit card in mere seconds. However, if I've got an unconscious patient and I want to send the images of their expanding subdural haemorrhage to the nearest neurosurgeon for rapid management stratification, then I must think twice.

I recognise that we have exemplary clinical photography departments in our hospitals. I understand that there are singular examples of where clinical messaging is done well in parts of Australia. But in a day and age where I can instantly videoconference with my nearest and dearest, it seems unreasonable to don my stethoscope and be forced to deprive my patients of these same technological benefits. We are in an age of clinical medicine where the use of smartphones at the point of care is not fringe practice or cutting-edge medicine. It's here and now, and we ignore the implications of this fact at our own peril.

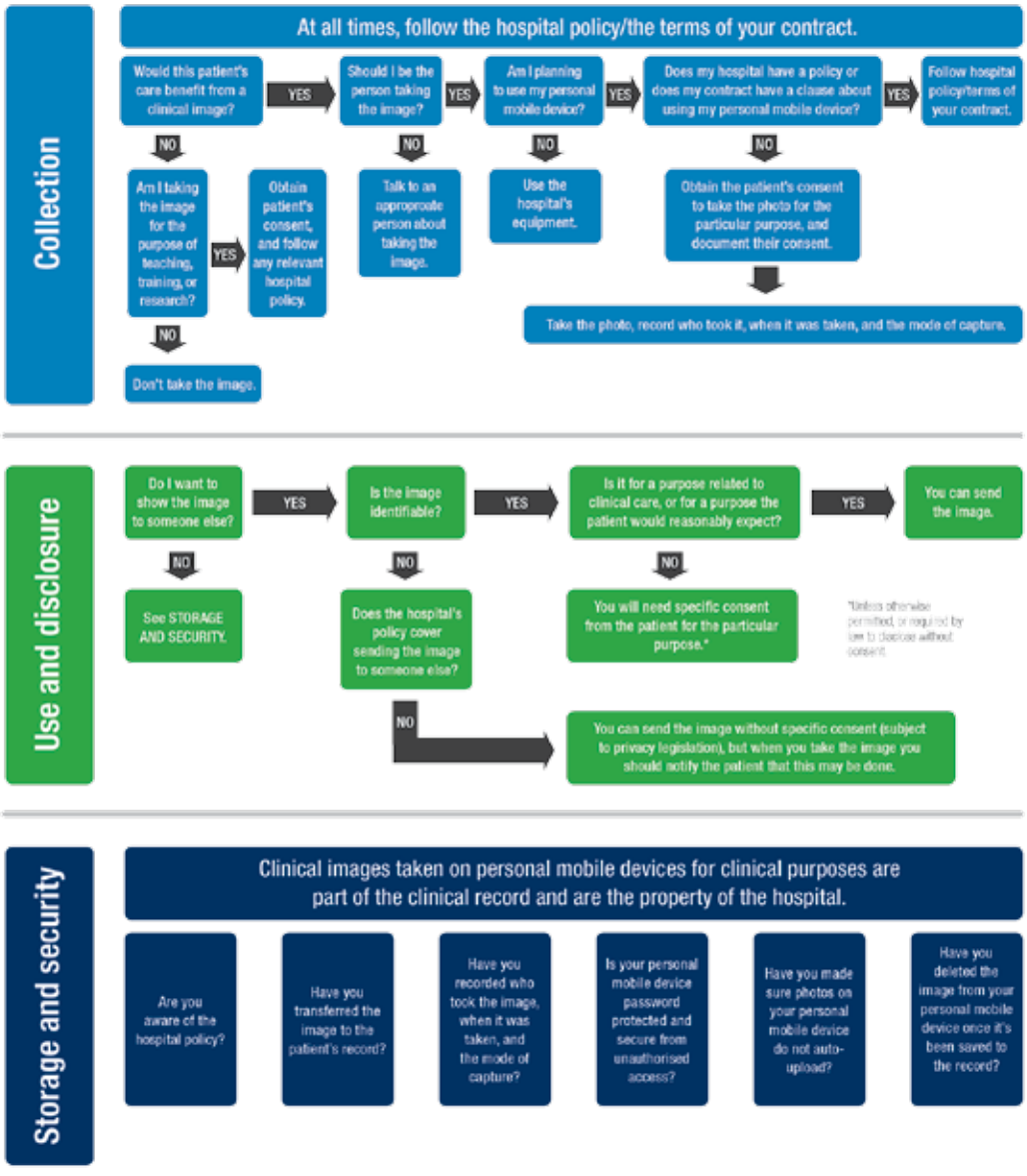

Figure 1. AMA decision-making process flowchart. Reproduced with permission from AMA

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Is surrogacy legal in Australia?

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As Dana Magdassi, a surrogacy lawyer from Ukraine, put it succinctly at the recent Australian Surrogacy Conference: 'IVF is a medical process. Surrogacy is a legal process.' At its best, surrogacy is an absolutely magical process. To hear a judge tell parents who have struggled with infertility for years that the child is theirs and to congratulate them is one of the most joyous experiences I could have as a lawyer. Informed consent to a surrogacy arrangement by the surrogate, her partner and the intended parents requires a range of information to be supplied: medical, psychological and legal.

Surrogacy regulation in Australia

Every state and the ACT allows altruistic surrogacy, and criminalises commercial surrogacy. Common features involve independent legal advice and psychological counselling/screening at the beginning, followed by consideration by the relevant IVF unit's ethics committee. The Northern Territory has no laws concerning surrogacy, and its only clinic does not provide surrogacy services.

Each jurisdiction has invented slightly different wheels as to surrogacy regulation. For example, in Queensland and New South Wales, it is necessary to obtain an affidavit from the treating doctor to show that the intended surrogate (and if a lesbian couple, both women) is an eligible woman; and to show that conception occurred after the surrogacy arrangement was signed. The latter is helped by a world-leading case, *LWV v LMH* (2012),[1] from Queensland, in which conception was held to be the act of pregnancy, not the act of fertilisation of the ova. In Victoria, by contrast, an affidavit by the doctor is not required, but a report by the doctor to the state regulator, the Patient Review Panel, is required before treatment can commence.

Doctors who practise in IVF must comply with the National Health and Medical Research Council (NHMRC) Guidelines, plus other Commonwealth, state and territory law. Doctors who practise assisted reproductive technology (ART) in Victoria and Western Australia are burdened with the most detailed state laws.

Why Australians go overseas

Many Australians venture overseas not because they cannot find a surrogate or an egg donor, but because the law in their jurisdiction discriminates against them in their bid to be parents. While surrogacy is the option of last resort for heterosexual couples, it is the first and only option for gay couples and single men to become parents.

Aside from discrimination, the reasons clients report for going overseas are primarily that they cannot find surrogates or egg donors here. Sometimes they believe the stories they read on the web about overseas success stories. The numbers of children born overseas vary, between 200 and 1000 a year. The estimate given by a surrogacy advocate recently was that there were 35 children born locally via surrogacy in 2014, and in the same year 400 overseas.[2] Intended parents often view regulation of surrogacy here as being too uncertain, too costly, cumbersome and slow. The reality is that the legal regime in Australia is generally simpler, considerably cheaper and just as fast as anywhere overseas (I tell intended parents to expect the process to take between 18 months and four years, depending largely on medical issues). Intended parents might spend approximately $25 000–60 000 on a typical domestic surrogacy journey. An estimate for Canada is about $90 000, and greater in the USA.

Table 1. Discrimination explained by state.

Jurisdiction	Discriminatory?	How?
Qld	No	
NSW	No	
ACT	Yes	Both the intended parents and surrogate and her partner must be couples
Vic	No	
Tas	Yes	Unless dispensed by order, all parties must live in Tasmania
SA	Yes	Surrogacy is confined to heterosexual couples, ART even more confined (currently under review)
WA	Yes	Surrogacy is confined to heterosexual and lesbian couples and single women; not available to single men and gay couples
NT	Yes	Surrogacy in effect is not available. ART is limited only to those eligible in South Australia

Flexibility between states

Some states allow IVF to occur elsewhere. This has led to intended parents undertaking IVF for New South Wales arrangements in Queensland, for example, or Queensland and New South Wales intended parents accessing US egg donors and having the IVF there, and then obtaining surrogacy parentage orders in Queensland and New South Wales courts.

Importing embryos from overseas can be problematic, under both national and some state requirements.

Going overseas for surrogacy

In advising patients that surrogacy is an option, doctors have to be careful not to commit offences when discussing overseas options. In Queensland, for example, to aid, abet, counsel, procure or to conspire with someone who will be committing a criminal offence, is also to be a principal offender. Other states have similar criminal laws. The maximum penalty for imprisonment is that of Queensland: up to three years. The maximum fine is in New South Wales: up to $110 000.

In two jurisdictions, there are two specific offences aimed directly at doctors and lawyers:

- In Western Australia it is an offence to provide a service knowing that it is to facilitate a surrogacy arrangement that is for reward (which includes overseas arrangements), except if the service is provided to the surrogate after she becomes pregnant.
- In Queensland it is an offence to provide a technical, professional or medical service to a surrogate in a commercial surrogacy arrangement (which includes overseas arrangements) before she becomes pregnant.

Table 3. Where can patients have ART for their domestic surrogacy arrangement?

Jurisdiction	ART anywhere?	Can the embryo be created outside the jurisdiction and transferred in the jurisdiction?
Qld	Yes, but doctor will have to be qualified expert for court	Yes
NSW	Yes, but doctor will have to be qualified expert for court	Yes
ACT	No	Yes
Vic	No	Yes, importation may need Victorian Assisted Reproductive Treatment Authority (VARTA) approval
TAS	Yes, but doctor will have to be qualified expert for court	Yes
SA	No	No
WA	No	Yes, importation may need Reproductive Technology Council (RTC) approval
NT	No	No

Going overseas for egg donation

Commonwealth, state and ACT *Human Cloning Acts*[4] make it an offence, punishable by up to 15 years imprisonment, to pay an egg donor other than her out-of-pocket expenses. Because state and ACT *Human Cloning Acts* exist, many intended parents who have gone overseas for egg donation will have inadvertently committed the offence under the state legislation, by virtue of long-arm laws; that is to say that they stretch out from the state like a long arm, extending the jurisdiction. Similarly, state and territory long-arm provisions extend to the *Human Tissue Acts*, which prohibit the sale of eggs, sperm or embryos. Doctors who have advised those patients to go overseas for commercial egg donation may also have committed the same offence, by virtue of principal offender laws. With careful legal planning, it is possible for patients to avoid committing these offences. Doctors need to take care as to what steps they take and what they say to patients, to avoid committing the offences.

Overseas altruistic surrogacy

Recently, I acted for a surrogate and her husband. My client was the surrogate for her sister and brother-in-law. A fairly straightforward arrangement, one might think. The complexity was that my clients lived in Adelaide and the intended parents lived in New Zealand. IVF was in the US. To enable this surrogacy to proceed, it required navigation of South Australian, Commonwealth, New Zealand and US law and the Hague Intercountry Adoption Convention. I drafted a surrogacy arrangement. It was non-compliant with South Australian law (because the intended parents did not live there, and because IVF did not occur there) and therefore an order could not be obtained in South Australia. However, the arrangement was legal. It was not commercial surrogacy, as the document made plain. An obstetrician in Adelaide was able to assist my client. The child was born, travelled to New Zealand, and lived with her parents. An order was made in a New Zealand court to recognise the intended parents as the parents. A good news story!

Table 2. Offences of entering into a foreign commercial surrogacy agreement.

Jurisdiction	Is it an offence?
Qld	Yes, and to make payment under it
NSW	Yes
ACT	Yes
Vic	No
Tas	No
SA	It may be, and may also apply to overseas altruistic surrogacy (following changes to the Family Relationships Act 1975 in 2015)
WA	It may be[3]
NT	No

What's next?

It is likely that the number of domestic surrogacy arrangements will continue to rise, as intended parents realise surrogacy is available. However, the vast majority of intended parents will likely continue to go overseas, due to a shortage of (or perceived shortage of) surrogates and donors.

It is likely that any changes that might come about from the recent House of Representatives surrogacy inquiry will not alter the fact that most Australian intended parents will still go overseas for surrogacy,[5]

Table 4. Long-arm provisions.

Jurisdiction	*Human Cloning Act*	*Human Tissue Act*	Long-arm
Commonwealth	*Prohibition of Human Cloning for Reproduction Act* 2002, ss.21, 24	N/A	N/A
Qld	*Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act* 2003, s.17	*Transplantation and Anatomy Act* 1979, s.42	*Criminal Code* 1899, s.12
NSW	*Human Cloning for Reproduction and Other Prohibited Practices Act* 2003, s.16	*Human Tissue Act* 1983, s.32	*Crimes Act* 1900, s.10C
ACT	*Human Cloning and Embryo Research Act* 2004, s.19	*Transplantation and Anatomy Act* 1978, s.44	N/A
Vic	*Prohibition of Human Cloning for Reproduction and Other Prohibited Practices Act* 2003, s.17	*Human Tissue Act* 1982, ss.38, 39	N/A
Tas	*Human Cloning for Reproduction and Other Prohibited Practices Act* 2003, s.20	*Human Tissue Act* 1985, s.27	N/A
SA	*Prohibition of Human Cloning for Reproduction Act* 2003, s.16	*Transplantation and Anatomy Act* 1983, s.35	*Criminal Law Consolidation Act* 1935, s.5G
WA	*Human Reproductive Technology Act* 1991, s.53Q	*Human Tissue and Transplantation* Act 1982, s.29	*Criminal Code* 1913, s.12
NT	N/A	*Transplantation and Anatomy Act*, ss.22E, 22F	*Criminal Code*, s.15

rather than at home. The inquiry has recommended making it more difficult for intended parents going to countries that don't have Australian standards. That's everywhere except the UK and New Zealand! It is unclear if Canada and the US will be in this category or not. The Committee recommended keeping the ban on commercial surrogacy, having national, non-discriminatory laws, and inquiring whether children born from donors and surrogacy have the names of the surrogates, donors and their partners on the children's birth certificates.

The Committee has recommended a national surrogacy register, so that intended parents can find surrogates. In short, if these proposals were to work, for every surrogate available in 2014, 11 would have to be found each and every year thereafter to replace overseas surrogates. If the Committee's recommendations were to be successful in this, it would be akin to the second miracle of the loaves and fishes.

For the last five years, the Hague Conference on Private International Law (of which Australia is a member) has looked at there being a Hague Convention in place concerning children, including international surrogacy arrangements. It remains unclear if there is going to be a convention, but my best estimate is if there is going to be a convention, it is likely to be three to five years away, and focused on the legal status of the child, more so than regulating how international surrogacy occurs. We shall see.

Finally...

Too often, I am told by clients that they have received insufficient advice by their treating doctor about the real chances of getting pregnant, and little to no information about surrogacy. As treating doctors owe a duty of care to their patients, sooner or later a patient who has undertaken innumerable IVF cycles will seek to sue her treating doctor for failure to give advice. It is only a question of time. Doctors should document the advice they have given to patients about the real chances of pregnancy, and other available options, including surrogacy.

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A model for consent: shared decision-making

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Doctors work in an increasingly complex environment: medical knowledge is continually expanding; patients have increased access to medical information via the internet; and there are increasing expectations of clinicians by patients and their families. This makes decision-making more complex and challenging for clinicians and their patients.

There is also a growing awareness of the Code of Health and Disability Services Consumers' Rights Regulation (Code of Patient Rights), which is reflected in the increasing number of complaints lodged with the Health and Disability Commissioner (HDC) against healthcare providers every year. In 2015, the HDC received 112 complaints related to consent.[1]

One of those complaints (14HDC00307) involved Mrs A, a 46-year-old woman who was booked for an elective total hysterectomy for adenomyosis. She also suffered from catamenial epilepsy, although Mrs A denied ever being advised of this diagnosis. In theatre, just before anaesthesia, Mrs A was approached by Dr B regarding bilateral salpingo-oophorectomy (BSO) in order to treat catamenial epilepsy. She signed the consent form, but later complained to the HDC. Mrs A explained to the HDC that she felt immense pressure to make a decision. The Commissioner found:

- The manner in which Mrs A's consent was obtained for the BSO was not appropriate. The operating theatre was not an appropriate environment for the informed consent process to take place, and did not allow for effective communication between Mrs A and Dr B. Accordingly, Dr B breached Right 5(2) of the Code of Patient Rights.
- Furthermore, Mrs A was not given sufficient time to consider whether she wished to have a BSO, and was not in a position to give informed consent to the removal of her ovaries. Accordingly, Dr B breached Right 7(1) of the Code.
- An adverse comment was made that Dr B did not appear to have communicated clearly to Mrs A that he had diagnosed her with catamenial epilepsy.
- No criticism made of Dr B's clinical care.

This case demonstrates some of the potential pitfalls in consent. In this article, I will explain the three key principles of valid consent, before discussing the model of consent as shared decision-making.

Valid consent comprises three key principles:[2]

1. The patient must be competent. Mental capacity is decision specific. Assessment of a person's capacity should be based on their ability to understand, retain and weigh up the information relevant to a particular decision. The person must also be able to communicate the decision. A patient who is unable to make a decision about a complex proposal is not necessarily incapable of making any decisions at all, and may

Code of Patient Rights

RIGHT 5: Right to Effective Communication

1) Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided. Where necessary and reasonably practical, this includes the right to a competent interpreter.
2) Every consumer has the right to an environment that enables both consumer and provider to communicate openly, honestly, and effectively.

RIGHT 6: Right to be Fully Informed

1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including:
   a) an explanation of their condition; and
   b) an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and
   c) advice of the estimated time within which the services will be provided.
2) Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.

RIGHT 7: Right to Make an Informed Choice and Give Informed Consent

1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.
2) Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent.
3) Where a consumer has diminished competence, that consumer retains the right to make informed choices and give informed consent, to the extent appropriate to their level of competence.

be perfectly able to consent where the issues are simpler. The starting point in the case of adults is always to presume that the patient has capacity to consent until it is shown otherwise.

2. The patient must have sufficient information to make a choice. Without adequate information, patients are unable to make decisions about their treatment. The information provided should, for example, include: an explanation of the investigation, diagnosis or treatment; an explanation of the probabilities of success, or the risk of failure; or harm associated with options for treatment. The patient should be given time to ask questions. The Medical Council of New Zealand (MCNZ) and the HDC (Right 5) expect patients to be given all information material to their decision, with the proviso that it would not cause the patient serious harm.
3. The patient must be able to give their consent freely. Pressuring patients into consenting to treatment invalidates the consent. To ensure that consent is freely given, patients should, where possible, be given time to consider their options before deciding to proceed with a proposed treatment. Be aware, too, that patients' friends and relatives may also try to exert their influence and that this can be subtle, but nevertheless powerful.

The MCNZ states, 'Informed consent is an interactive process between a doctor and patient where the patient gains an understanding of their condition and receives an explanation of the options available including an assessment of the expected risks, side effects, benefits and costs of each option and thus is able to make an informed choice and give their informed consent.'[3]

Consent as shared decision-making

The best approach to consent is one of shared decision-making. Neither the paternalistic model of care where 'doctor knows best' or a purely informative approach of, 'here's all the information, you decide' are appropriate to informed consent. A better model is shared decision-making.

Shared decision-making is a process in which clinicians and patients work together to select tests, treatments, management or support packages, based on clinical evidence and the patient's informed preferences. It involves the provision of evidence-based information about options, outcomes and uncertainties, together with decision support counselling and a system for recording and implementing patients' informed preferences.[4]

Benefits of shared decision-making[5]

- Increases patient involvement in the decision-making process
- Increases patient knowledge and understanding
- Shares some responsibility for the decision with the patient
- Leads to more realistic expectations from treatment
- Ensures decisions and choices that align with patients' preferences and values
- Leads to, in some cases, better health outcomes
- Helps reduce geographical variations in care
- Improves patient satisfaction
- Improves adherence to treatment
- Increases the accuracy of patients' risk perceptions and makes them better informed
- Helps identify the high-risk decision

Consent is a process

Shared decision-making places the individual patient at the centre of the process. The goal is to arrive at a decision that is right for the individual patient, from their perspective, which may not be the treatment option that the clinician believes to be the best.

Often clinicians approach consent as an event when the patient signs the completed consent form. Completed consent forms provide some evidence that consent was obtained, but mean little beyond that – it is important to realise that they do not constitute proof that the consent was valid. If there is any dispute over whether valid consent was obtained, the key issue will not be whether the patient signed a form or not, but whether they were given all the information they needed to make a considered decision.[2]

Consent is more accurately viewed as a process. Patients need time to absorb information, ask questions and weigh up the benefits of a procedure against the potential adverse outcomes. The circumstances surrounding the procedure will affect the degree to which patients wish to be involved. In the acute setting, the patient is more likely to place the responsibility for the majority of the decision-making with the clinician. In situations where a procedure is elective and not mandatory, it is advisable to take the time to ensure that all the information that the patient needs to make the decision is carefully explained. This includes the possible adverse outcomes that may be rare, but of high importance to that specific patient. Be aware that should the patient experience an adverse outcome from their treatment, their preference about how much they should have been told and involved may well be different in retrospect and so can change over time.[5]

Verbal or written consent?

The Code of Patient Rights requires written consent in the following situations:

Right 7 (6) Where informed consent to a healthcare procedure is required, it must be in writing if:

a) The consumer is to participate in any research; or
b) The procedure is experimental; or
c) The consumer will be under general anaesthetic; or
d) There is a significant risk of adverse effects on the consumer.

Outside these situations, whether verbal or written consent is given, it is crucial that the key points of the discussions with the patient are documented in the medical record.

Consent is not always a straightforward process. Organisations, such as District Health Boards, have policies on consent that ensure the patient and clinicians are protected. Following a robust process will help to avoid a later complaint. It is also advisable to contact your medical defence organisation if you have any concerns regarding consent and wish to discuss them further.

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Informed consent in antenatal and intrapartum care

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"…her evidence indicates that it was her policy to withhold information about the risk of shoulder dystocia from her patients because they would otherwise request caesarean sections…"

Lords Kerr and Reed commenting on the obstetrician's modus operandi to disclosure of risks in antenatal care.[1]

'Informed consent' is one of two fundamental preconditions for doctors undertaking actions that would normally be classified as criminal acts, typically as trespass or assault. The other precondition is 'indication', that is, a valid medical reason or justification for intervention.

Both preconditions are subject to a number of influences we often fail to consider. Indication is the easier of the two, since it is almost exclusively determined by objective, scientific fact and professional consensus. However, it is important to recognise that indication is not static, given that scientific progress will alter the limits of what is accepted professionally as 'good medicine'. Fast progress in medical knowledge can necessarily lead to a mismatch between the scientific state of the art and current practice. The greater the mismatch, the greater the medicolegal risk for the practitioner. We contend that, at this point in time, the issue of maternal birth trauma is an excellent example of such a mismatch.

The situation is even more complicated for the precondition of consent. Importantly, informed consent also requires that scientific progress be taken into account. We are obliged to provide up-to-date and accurate information for consent to become truly informed, and we all know how precarious that distinction may be. However, when it comes to informed consent, we are also beholden to another set of professional influences that are entirely outside our control: the law.

The law is subject to the same societal influences as medicine, and it is at least as fluid, even though some components of it have been in place for millennia. The fluidity of the law and its application in medical practice is most evident in highly charged areas such as termination of pregnancy and surrogacy/assisted reproduction. Legislation and judiciary decisions necessarily reflect the zeitgeist; the 'spirit of the times'. Things that were once legal become illegal, and vice versa.

Recent changes to the legal meaning of obstetric informed consent

Occasionally the judicial system throws up something unexpected, which produces a reflection of the zeitgeist that changes the rules of the game altogether. This is what occurred in March 2015 with the Montgomery v Lanarkshire decision of the UK Supreme Court,[1] which is the motivation for this piece (see Table 1).

This decision has, for the first time in history, defined an attempt at normal vaginal birth as a procedure or a treatment. In the past, an attempt to deliver vaginally was considered a natural process that did not require informed consent. Put plainly, to perform a 'legal' hysterectomy we generally have to discuss risks that may occur at a prevalence of well below 1:100, and, since Rogers v Whitaker,[2] we have a duty to warn of complications that are uncommon, if it is evident that the patient would consider a given risk significant. The Supreme Court, in Montgomery v Lanarkshire, formulates this principle as follows: 'The doctor is under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative... The test of materiality is whether… a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the patient would be likely to attach significance to it.'[1]

Since there are a multitude of complications of an attempt at vaginal birth that are very common at well above 1:100 and highly likely to be considered material by pregnant women, such risks now need to be disclosed in order to ensure that maternity care is of a defensible standard in the event of an adverse outcome. Most pregnant women (and their health professionals) would regard an emergency caesarean section (CS), forceps or a vacuum as a risk and a complication, even without the occurrence of postpartum haemorrhage (PPH), major perineal tears, levator tears or CS wound infections. Of equal import is the future morbidity associated with anal incontinence, prolapse, sexual dysfunction or psychological sequelae up to and including post-traumatic stress disorder.[3]

Table 1. Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland) [2015] UKSC 11 On appeal from: [2013] CSIH 3; [2010] CSIH 104.

Grounds for negligence	• Baby Montgomery was born in 1999 with severe disabilities following a difficult vaginal delivery complicated by shoulder dystocia. • His mother, Mrs Montgomery, attributed the injuries to negligence on the part of the obstetrician: she should have been given advice about the risk of shoulder dystocia involved in vaginal birth compared with an elective CS.
Statement of material facts	• Mrs Montgomery had a degree in molecular biology and worked as a hospital scientist. Her mother and sister were both GPs. • Her risks for shoulder dystocia included: – Short stature ('just over 5 feet') – Primigravida – Insulin-dependent diabetes mellitus • She attended a diabetic obstetric unit for her antenatal care (ANC). Her doctor, a consultant O&G, was responsible for both the ANC and her labour. • Her antenatal counselling included: – The estimated fetal weight (EFW) from a final ultrasound at 36 weeks predicted 3.9kg at 38 weeks. – At 36 weeks, the patient told her doctor she was worried about the size of baby. – Advised there was recourse to a CS if problems were encountered during labour. – She was counselled to have an induction of labour (IOL) at 38w5d with an attempt at vaginal delivery. • Her counselling did NOT include: – The ~10% risk of shoulder dystocia in a vaginal delivery. – The complications of shoulder dystocia; PPH (10%), 4th degree tears (4%), brachial plexus injury (0.2%) and cord occlusion with cerebral palsy/death (0.1%). • Intrapartum course: – IOL for several hours before the 'labour became arrested'. – Further augmentation was instituted. – A forceps delivery was performed in theatre with poor descent of the fetal head. – Shoulder dystocia ensued when half the head was outside the perineum. – The anaethetist gave a general anaesthetic for possible Zavanelli. Obstetrician decided on completing the vaginal delivery with severe head traction and (partial) symphysiotomy. – 12 minutes to delivery from shoulder dystocia. Birthweight 4.25kg. – The child has CP (dyskinetic), with all 4 limbs affected, attributed to a cord occlusion from deprivation of oxygen during delayed delivery and an Erb's palsy. • The Court concluded: 'If Mrs Montgomery had had an elective CS her son would have been born uninjured.'
Patient/ Obstetrician & Expert witness testimony	• Patient: – If she had known of the risk of shoulder dystocia then she would have requested a CS. – She said in evidence that she was 'not arrogant enough to demand a CS' when it had not been offered to her. • Obstetrician: – Agreed that the patient would have had a CS if the risk was mentioned and it was offered 'as would any diabetic today'. – She thought the risk of a 'grave problem' from shoulder dystocia was small and thus she did not mention it. – That if the condition is mentioned, 'most women will actually say, "I'd rather have a CS."' – 'If you were to mention to any mother… a very small risk of the baby dying in labour, then everyone would ask for a CS, and it is not in the maternal interests for women to have CS.' – She left out the 10% +/- in the EFW as then 'you would be sectioning virtually all diabetics'. – She waited for the patient to mention CS. She stated that if the patient had mentioned CS, she would have received it. • Expert witnesses: – Generally agreed that the obstetric care was in line with RCOG Guidelines. – Expert witnesses were divided over whether they would have counselled the patient about the risk of shoulder dystocia or would have waited for the patient to mention it.
Description of how law was applied to the facts	• The Court chose to depart from a decision based primarily on expert medical evidence to one on the basis of patient autonomy: – Consent to treatment proposed is not just one based on medical considerations. • Attempt at normal vaginal delivery was viewed as a 'treatment' with an alternative treatment available, namely CS.
Judicial summary from Lady Hale	• 'That is not necessarily to say that the doctors have to volunteer the pros and cons of each option in every case, but they clearly should do so in any case where either the mother or the child is at heightened risk from a vaginal delivery. In this day and age, we are not only concerned about risks to the baby. We are equally, if not more, concerned about risks to the mother. And those include the risks associated with giving birth, as well as any after-effects. One of the problems in this case was that for too long the focus was on the risks to the baby, without also taking into account what the mother might face in the process of giving birth.'[1]

What does this mean in practice?
Obstetric consent, whether ante- or intrapartum, is a difficult subject. Unfortunately, antenatal education may be provided by staff who underplay the possibility of obstetric interventions. As a result, the information provided is often inaccurate and biased, and likely to be seen as such in a court of law. In the interest not just of risk management, but also as a requirement of medical ethics under the general principle of patient autonomy, it appears imperative that such information be provided by staff trained to undertake those procedures, that is, obstetricians or obstetricians in training, and well before a crisis in the delivery suite makes true informed consent impossible.

This is particularly crucial whenever several treatment options are available. The Supreme Court, in Montgomery v Lanarkshire, has stated unequivocally that '...doctors have to volunteer the pros and cons of each option in every case... where either the mother or the child is at heightened risk from a vaginal delivery.'[1] One could add that the same necessarily applies to different forms of vaginal operative delivery.

Where there is limited provision of antenatal information, women are poorly prepared to participate in intrapartum decision-making, which is often emotionally difficult and under considerable time constraints. Operative delivery is a particularly important issue for consent, given the high probability of somatic maternal trauma.[4,5] In most cases of vaginal operative delivery there is (at least theoretically) the option of CS, and in most cases of forceps there is the option of vacuum delivery, with the exception of uncommon scenarios such as the after-coming head or premature birth. In most instances it is difficult to argue that forceps is without alternative, given that entire countries, such as Denmark,[6] have done without forceps for many years. Hence, the imposition of one option by the obstetrician, without discussion of alternatives, is potentially indefensible.

The issue of maternal trauma
Antenatal counselling of women who plan a vaginal delivery should include a reference to major pelvic floor trauma. The odds ratio of major tears of the levator ani muscle or 'avulsion', the main aetiological factor for pelvic organ prolapse,[7,8] in forceps delivery compared to vacuum is about five. Vacuum does not seem to convey an increased risk compared to normal vaginal delivery (NVD).[5] Anal sphincter tears are also much more common in forceps delivery compared to vacuum, with both more likely to lead to trauma than NVD.[9] Pelvic floor and perineal trauma does not occur with caesarean delivery and needs to be discussed when considering delivery options.

Obstetric practitioners who are insufficiently aware of the true incidence and implications of obstetric maternal trauma act at their own medicolegal risk. Levator trauma was virtually unknown until recently, as it is usually occult. The first clinical description dates to 2007.[10] Anal sphincter trauma is diagnosed increasingly commonly, but still appears to be overlooked more often than not. This may be due to truly occult trauma or poor diagnosis.[11,12]

Medicolegal consequences
Over the coming years there will be an increasing need to share information on the risk of perineal and pelvic floor trauma with patients (let alone risks such as shoulder dystocia in macrosomia, or stillbirth in VBAC) in order to offer a robust medicolegal consent procedure. This is particularly true since there is evidence of increasing institutional pressure to reduce CS rates.[13] A push to reduce CS rates has the potential to justify more aggressive obstetric measures designed to achieve vaginal delivery, such as rotational forceps, longer second stages and an emphasis on VBAC.[14] Demographic changes, especially increasing obesity and age at first delivery, make such aggressive obstetric practices increasingly dangerous to patients, and not just as regards pelvic floor morbidity.[15] By definition, using the CS rate as a performance measure of obstetric services is a break with the traditional use of morbidity and mortality as undisputed key performance indicators.[16] Treating the CS rate as such will inevitably result in increased morbidity and mortality, and likely, medicolegal claims. It is not surprising at all that law firms are starting to specialise in this field and market their services aggressively.[17] We have allowed obstetrics to regress into practices that increase the likelihood of complications leading to medicolegal action precisely at a time when judicial innovation has reduced the likelihood of contemporary practice being successfully defended in court. As Montgomery v Lanarkshire has illustrated, this may involve the consequences of events that occurred many years in the past.[1]

We hope to have made clear that obstetric services are poorly prepared to deal with currently accumulating liabilities. The solution to the impending novel avenues of litigation (and the obvious way forward in terms of better risk management) is to focus on fulfilling our ethical, moral and medicolegal responsibilities as regards informed consent. Maternity care is anachronistic in terms of consent because we have been treating pregnant women like minors. This will have to change.

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Effective communication reduces risk

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Obstetricians and gynaecologists have chosen a career that is both clinically rewarding and also inherently risky, medicolegally. While it is important to maintain clinical and surgical skills to the standards expected of RANZCOG, the Medical Council of New Zealand and the Medical Board of Australia, older studies of obstetricians and gynaecologists[1] and more recent ones of physicians[2] show that focusing only on 'technical' competence does not protect clinicians from complaints and claims.

The literature consistently shows that one of the main drivers for complaints and litigation is poor communication[3,4] and that patients often use clinicians' communication skills as a proxy marker for their technical competence.[5]

From the Medical Protection Society's (MPS) experience, one important way to effectively reduce medicolegal risk is by improving our skills as communicators. This includes:

- communicating effectively with a broad audience (patients, their families and our colleagues);
- communicating well using different means (verbally, non-verbally and in writing);
- communicating different content (breaking bad news, communicating risk and shared decision-making are areas that have been particularly well researched);
- establishing and managing expectations, both realistic and unrealistic; and
- establishing ways to check whether our communication has been understood.

A review of communication skills cites several barriers to good communication.[6] These include workload, deterioration in communication skills over time and reluctance of either the doctor or the patient to share information and decisions. While acknowledging the challenges that exist, this article aims to highlight strategies to help overcome these barriers that are both time-efficient and effective in reducing patient dissatisfaction.

Communication with patients

The communication behaviour of doctors within consultations has been well-studied and observed. A study by Rodriguez et al, for example, showed significantly fewer complaints for doctors who explained things clearly, gave enough information, were perceived as caring and kind, knew the medical history and spent enough time with the patient.[7] Several skills can be used to ensure you make a good impression with your patients, rather than a potentially misconceived view of a rushed, busy clinician with other things to do.
The opening phase of the consultation, sometimes termed the 'golden minute', is the best opportunity to create this good impression. The skills discussed, therefore, focus largely on the start of the consultation, but obviously can be applied at other stages. Most patients note the non-verbal skills of the doctor more than they report on other aspects.[8,9] For example, you seldom hear a patient saying, 'that doctor's examination skills were second to none.' You are far more likely to hear patients reporting, 'she was very kind' or 'he explained everything clearly to me'.

Greeting the patient with a smile and introducing yourself is an important start. Try to ensure eye levels are the same. The power differential between doctor and patient is never more marked than when the patient is lying down and the doctor remains standing. Interestingly, the simple task of seating yourself also creates an impression that you are spending more time with the patient.[10]

Part of the 'golden minute' skills involve patient-centred consulting through active listening and empathy. Patients have usually rehearsed a story before the consultation and there is good evidence that doctors often do not listen to this story and interrupt within the first 20 seconds.[11] This interrupting is often thought by the doctor to be time-efficient. By the patient, however, it may be perceived as rude or uncaring and creates a negative perception of the doctor. If uninterrupted, most patients will tell their story within 90 seconds and then feel that the doctor has listened to them.[12] Patients often provide important information in those 90 seconds, meaning that additional questions from the doctor become redundant. So, counterintuitively, it is often more time-efficient to listen without interrupting for the first 90 seconds, rather than rush into closed clinical questions.

Empathic skills involve noting cues and overtly responding to them with short 'touch and go' empathic statements such as 'that sounds difficult' or 'you must have been very frightened'. Empathic responses provide the patient with a receipt that you have heard and understood them, and enhance the impression of a clinician who is caring and kind. These statements are time-efficient and result in shorter consultations.[13] Following this with establishing the concerns and expectations of the patient will help to demonstrate a patient-centred approach.

Communicating with patients and their families

Sometimes it is not the patient who instigates the complaint, but a family member. Therefore, where possible and

where the patient gives consent, it is wise to involve significant family members in discussions around patient care where appropriate. The same principles of listening and empathising with family members can be used.

Discussions with patients and their relatives become particularly important when things have gone wrong. The use of effective communication skills as part of open disclosure can help reduce your medicolegal risk.[14]

Checking for understanding

No matter how good our communication with the patient may be, there is only one way to assess whether the intended audience has understood: ask. Three methods to check understanding are shown below (see Table 1). Kemp studied the ways that doctors check for understanding and clearly demonstrated that one method is most likely to lower medicolegal risk and is preferred by patients.[15]

Most doctors will check for understanding using the first two methods. However, the third method creates a 'shame-free' zone where, if patients do get something wrong, it implies the clinician is at fault for not having made things clear. This allows the clinician to correct the error without the patient feeling inferior. Interestingly, as well as offering the lowest medicolegal risk, Kemp's paper showed patients have a strong preference for the Tell Back-Collaborative approach.

Communicating with colleagues

The term 'medical jousting' has been coined to describe the staggering statistic drawn from a study in obstetrics and gynaecology suggesting that as much as 60 per cent of litigation is instigated at the suggestion of another healthcare professional.[16] Consideration therefore needs to be given to how we communicate with our colleagues as well as how we respond to comments made about our colleagues. The basic principles are that a good working relationship with colleagues is likely to lead to support for the patient and yourself, should an adverse outcome occur. The use of standardised and reliable techniques for clinical communication with colleagues has been well tried-and-tested in a variety of settings and is also well-described. Additionally, just as it is important for you to check the patient's understanding, there is evidence to suggest that asking colleagues to repeat back vital information can reduce errors.[17]

In summary

While there are some aspects of risk that are inherent to the clinical nature of the specialty of obstetrics and gynaecology, there are some risks that are modifiable, which largely relate to communication. By maximising verbal and non-verbal skills, doctors can exert some control over the impressions patients create of them. A doctor who is perceived by their patients as someone who listens, appears caring and kind and is focused on their needs, can go a significant way to reducing the clinician's individual medicolegal risk.

MPS, and its commercial arm, Cognitive Institute, offer a variety of workshops for clinicians wishing to further enhance their confidence and competence in communicating with patients and colleagues. As recognised leaders in communication skills training for healthcare professionals, MPS and Cognitive Institute offer short, practical skills courses for busy clinicians as well as more in-depth programs.

More information is available at www.medicalprotection.org/newzealand and www.cognitiveinstititue.org.

Table 1. Three methods to check patient understanding.

1. I've given you a lot of information. Is there anything you don't understand?	Yes–No
2. It's important that you do this exactly the way I explained. Could you tell me what I've told you?	Tell Back-Directive
3. I've given you a lot of information. It would be helpful for me to hear your understanding about your condition and its treatment.	Tell Back-Collaborative (preferred)

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Issues of consent for fetal pathology

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The principles of consent, with respect to diagnosis and treatment, apply equally to the field of obstetrics as to other areas of medicine. However, several complexities arise where pathological examination of the fetus or products of conception are concerned. This article focuses primarily on the stillborn fetus and associated umbilical cord, membranes, placenta and amniotic fluid, where some of the consent issues are governed by the various legal requirements and laboratory accreditation standards.

Consent

For early termination or miscarriage (less than 20 weeks gestation) the fetus and fetal tissue are regularly referred to pathology services for examination. While written consent is not usually legally required, it is good practice to obtain the consent of the mother using a fit-for-purpose consent form. This form should include clear descriptions of the options in terms of the extent of examination to which consent is being given, ancillary testing (such as genetic testing and its implications), and options for return of organs to the body and return of the body to the family. Queensland Health provides such a form.[1]

The clinician obtaining consent should have an understanding of the legal requirements in their own jurisdiction. For stillbirths of 20 weeks gestation and beyond, Coronial Act requirements apply in most jurisdictions and if the newborn has shown signs of life, birth and death certificates are required.

In some jurisdictions, consent for a fetal autopsy can be encompassed within the usual autopsy consent form. The Stillbirth and Neonatal Death Alliance of the Perinatal Society of Australia and New Zealand is developing an update of the Perinatal Mortality Guidelines, which include matters such as the consent required for an autopsy. One difficulty is that the various consent forms for the jurisdictions differ and attempts to harmonise them have been deemed too difficult. In addition, the Guthrie card collection that is performed for all newborns is now almost routinely done for all stillbirths. However, if parents do not consent to an autopsy, consideration may be given to not performing the Guthrie card tests.

Recent developments in diagnostic genetics, such as comparative genomic hybridisation (CGH), exome or whole genome testing, require particular care in the area of consent. Increasingly, incidental findings may arise with implications for living relatives that are unrelated to the cause of the fetal death. For example, the cause of death in a stillborn may be placental abruption, however CGH microarray may reveal copy number variants unrelated to the stillbirth, but known to cause intellectual disability or other serious conditions. This is especially important to consider as almost all perinatal units have moved to routine CGH array testing rather than cytogenetics. The Royal College of Pathologists of Australasia provides guidance relating to incidental genetic findings.[2] If an abnormality is discovered upon testing of the fetal tissue, genetic testing may be carried out, preferably following counselling by clinical geneticists.

In the case of stillbirth or perinatal death, all products of conception should be sent to the pathology service with the fetus/body and included within the above consent procedure. Where the baby is living, but there are other indications such as prematurity, maternal or fetal/neonatal complications or abnormalities, placental pathology should be requested, although no specific written consent procedure is required. Where fetal cells are to be stored or propagated in tissue culture, or tissues or cells are to be used in human transplantation, specific consent is required.

Storage/disposal/return to family

Fetal tissue derived from pregnancies of less than 20 weeks gestation is subject to the same storage and disposal requirements as other human tissue under National Pathology Accreditation Advisory Council Guidelines;[3] that is, unused wet tissue is retained by the laboratory for a minimum of one month and paraffin-embedded tissue in blocks and histological slides for ten years. If the infant has lived, retention requirements extend to paediatric requirements, which are once again one month for wet tissue, but 25 years for blocks and slides. Nevertheless, good practice is for both the perinatal autopsy consent process and the pathology service to provide options where physically possible. This includes return of organs to the body and return of the body to the family and some jurisdictions also allow for various combinations of tissues, blocks and slides to be returned to the parents at any stage following an autopsy (although the limitations on future diagnostic possibilities should be pointed out to the family if this is to occur). It is also good practice for the pathology service to have a means to respectfully dispose of all human tissue, in particular, fetuses at less than 20 weeks, and many provide cremation services in which families can participate. Fetuses over 20 weeks gestation are subject to all legal requirements for burial or cremation in each jurisdiction, although blocks and slides will generally be retained as mentioned above.

Research

The National Health and Medical Research Council (NHMRC) developed the National Statement on Ethical Conduct in Human Research,[4] which provides extensive guidance on this topic with respect to pregnancy. It has separate guidance on gametes, embryos and/or participants in assisted reproductive treatments,[5] while conduct around embryos excess to the needs of those for whom they were created using assisted reproductive technology is covered by Australian legislation.[6]

The NHMRC Statement describes potential conflicts of interest between research and clinical care and makes particular reference to terminations of pregnancy, where the possibility of research must not be considered until a decision to terminate has been made. It also advises having separate consent forms and processes for clinical care versus research, suggesting that different (qualified) individuals obtain these consents.

Researchers are advised to discuss with the woman the possibility of involving others for whom the research may have implications and appropriate counselling and support should be available. Any storage of the fetus or fetal tissue for later use in research should comply with the principles outlined above and be specifically consented to. If there is any potential for commercial application of outcomes of the research, including the development of stem cells or cell lines, this should be pointed out along with the advice that the mother will receive no benefit. All commercial trade in human tissue is illegal and use for education, quality and training is governed by the various jurisdictional Acts.

Conclusion

Access to perinatal autopsy is a vital part of any obstetric service and is a complex area in terms of consent, particularly in a situation of great distress for mothers and families and the workload-pressured environment of an obstetric unit. Despite the complexity, it is vital to follow some general principles for legal, clinical and compassionate reasons. The pathology service may be able to assist in decision-making and should be consulted where there are concerns. The service will most likely have options to conserve the tissue while these important issues are being clarified and is accustomed to assisting clinicians in these difficult situations.

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A psychiatrist's role in times of doubt

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Psychiatrists are able to assist their gynaecological colleagues should any doubt exist regarding a patient's ability to give informed consent for a particular medical or surgical intervention. In particular, two scenarios need to be considered:

1. when there is a suspicion that a patient's mental condition or cognitive capacity compromises their ability to give informed consent; and
2. when a patient being treated as an involuntary patient needs non-psychiatric medical/surgical treatment.

Informed consent is considered to be given when a patient agrees to a proposed course of management based on their participation in a risk-benefit analysis. This requires that a patient acting autonomously must be competent to understand and decide for themselves, be free of any third-party coercion and be provided with all the relevant facts to make a decision. Those facts should include disclosure of the expected outcome of non-treatment, the risks of the proposed treatment and the expected benefit, and the risks and benefits of any alternative treatment. We need to remember that patients have both an ethical and legal right to make bad decisions, although most treatment refusals and withdrawals of consent to treatment are based on disruptions in the doctor-patient relationship. Communication problems between doctor and patient, lack of trust of the treating source and psychopathologic factors may all play a role. However, many medical practitioners are likely to attribute such dissonance to a patient's lack of capacity or competence.

In Australia, the legal requirements involved in obtaining informed consent are principally derived from the law of negligence, as modified by statute. It is the medical practitioner's legal duty to communicate to a patient who is considering a medical intervention the material risks of the proposed intervention. In Australia, two main legal principles will be considered:

1. Did the medical practitioner disclose the pros and cons of each of the possible courses of management, and in particular, all of the risks that a reasonable person in the patient's position would be likely to attach significance to?
2. Did the medical practitioner disclose all of the risks of the possible courses of management that they knew, or should have known, the particular patient would attach significance to?

These requirements may seem rather onerous, but there is nothing in the above that sits outside of what is considered to be good medical practice. Obtaining consent involves good communication with patients that is positively beneficial in its own right, through increasing patient understanding, managing expectations, improving compliance and fostering a sense of empowerment and control. These principles are subject to what is referred to as 'the therapeutic privilege'. That is, a medical practitioner is said to be justified in withholding information when they judge on reasonable grounds that the patient's health, physical or mental, might be seriously harmed by the information. Although this exception to the general rule may appear to be of particular relevance to management of the mentally ill, in practice it is hardly ever employed. Its limits are unknown and reliance on it would be fraught with peril.

The first principle is covered by disclosing to the patient all known risks (including risks speculated in the medical literature) no matter how unlikely or unusual. As for the second, all that you have to do is ask the patient 'do you have any specific concerns regarding the proposed treatment?'

Beneficence alone is no longer adequate. Within such doctrines were the imperative that medical practitioners have an ethical obligation to act, to the best of their judgment, for the benefit of patients, while at the same time doing no harm. There is nothing wrong with this sentiment. However, historically, the ethos of 'doctor knows best' prevailed: patients were required to be obedient if they wished to receive treatment, and moral deception was considered justifiable. Things have changed since the middle of last century and the principle of autonomy has prevailed. It holds that a patient has the right to protect their bodily integrity, and is entitled to evaluate the different risks and dangers associated with each medical decision before making their choice.

Key points

Psychiatrists can assist their gynaecological colleagues to ensure that a patient is able to give informed consent for a medical procedure should any doubt exist regarding capacity to provide such consent. This involves establishing that the elements of competence, voluntariness, disclosure, recommendation, understanding, decision and authorisation have been addressed. Should a particular patient be unable to give informed consent due to mental impairment, a surrogate or third party may be legally authorised to consent to treatment on their behalf. In cases of emergency, in particular if an intervention is considered to be life-saving, treatment may proceed without informed consent. Clear and detailed documentation of the process in which informed consent is established or contested is essential.

The bioethicists Beauchamp and Childress suggest that there are seven key elements that constitute the principle of informed consent:

1. Competence
2. Voluntariness
3. Disclosure
4. Recommendation
5. Understanding
6. Decision
7. Authorisation

Competence refers to a patient's ability to understand a treatment option, deliberate regarding its risks and benefits, form a decision based on this deliberation and communicate their decision adequately. Should a patient be a minor (variously defined across different jurisdictions) or be deemed mentally or psychologically incompetent, a third party or surrogate may be required to make a decision on their behalf.

Voluntariness refers to the idea that a person acts voluntarily if they will an action in the absence of external constraints and coercions. However, surrogate decision-makers may be authorised to make treatment decisions when the patient is deemed to lack the competence to make decisions on their own behalf that are conducive to their best health outcome.

Disclosure refers to the provision of all relevant information regarding the condition, the prognosis, the possibilities of management and recommended course of action, together with information as to the material risks and benefits of any proposed treatment, alternative treatment or non-treatment. As a matter of principle, the following must be considered:

- The nature of the risk (what is it?)
- The magnitude of the risk (how big is it?)
- The probability the risk might materialise (how likely is it?)
- The imminence of risk materialisation (when will it happen?)

Recommendation refers to informing the patient of the opinion of the medical practitioner for the best treatment option.

Understanding is a much more vexed issue. A clinician cannot presume that the provision of medical information results in any particular patient appreciating the full nature and implications of any proposed treatment. Here we advise that the provision of information and the seeking of a decision and authorisation for such treatment be separated in time, where feasible. A patient needs to be given time to contemplate what they have been advised and have the opportunity to clarify any concerns or any misunderstanding that they may have. The medical practitioner should explore the patient's understanding of the risks involved in the treatment and of the implications of non-treatment or alternative treatment before a decision is made.

A medical practitioner discusses treatment options with a patient and her partner.

Any decision to proceed with treatment needs to be made by a patient free of coercion, undue persuasion, manipulation by (misinformation or otherwise) and maleficence. Once such a decision is made it needs to be adequately communicated. Prior to surgery it has become mandatory that an informed consent to treatment form is signed. However, the evidentiary value of this form is limited if all that is disclosed by such a signature is that a discussion has occurred while revealing nothing as to what was discussed with the patient. Detailed clinical documentation of what transpired during the process of obtaining informed consent is essential. In some circumstances it may also be useful for this process to be witnessed by a third party.

Mental illness or psychological disturbance can compromise any or all of the above seven key elements. However, just because a person is unable to make informed decisions regarding their mental health, it does not mean they are incompetent to make decisions regarding their physical health. For example, a woman may be suffering from a psychotic illness that compromises her ability to appreciate that she is mentally unwell, yet at the same time she may properly be able to consent to a dilatation and curettage to address her menorrhagia.

> 'All patients are presumed to be competent to consent until it is demonstrated that they are not.'

It is an incorrect assumption that people with a mental illness are uniformly deficient in decision-making abilities and it should be considered that impairment of decision-making may be selective. In each and every case, an individualised assessment of residual capacity must occur. Many patients with severe mental illness are unable to recognise they are mentally unwell or psychologically impaired; however, this does not necessarily mean that they are unable to recognise that they are physically unwell and in need of treatment. The question of competence is specific to the decision that needs to be made. Just because a patient disagrees with a medical practitioners' opinion, it does not mean that they lack the ability to understand. A psychiatrist is able to assist other medical practitioners to ascertain that any particular patient within any healthcare scenario is able to give informed consent for the proposed treatment or whether any of the aforementioned key criteria cannot be met.

While competence can be seen in absolute terms (it either exists or it does not), capacity exists on a spectrum between the highly educated, materially secure, physically and mentally unimpaired mature adult to the illiterate, poor, physically unwell, depressed, brain-injured person suffering chronic pain and under the influence of medication or other substances. A competent patient may have a reduced capacity to make decisions. Factors that may affect competence and capacity to consent include: being under the influence of alcohol or drugs (prescribed, over-the-counter or illicit); delirium; cognitive impairment through dementia or other progressive neurological disease; intellectual disability; brain injury; communication disability; pain; fatigue; sleep deprivation; anxiety; depression and psychosis. Impairment of capacity to consent may also fluctuate.

In Australia, each state and territory has a Mental Health Act that determines that a person with a mental illness may be treated against their will if they do not have the capacity to recognise they need treatment and are a risk to either themselves or others, or risk further deterioration in their physical or mental health. Such treatment needs to occur in the least restrictive environment and be subjected to an external review process.

Should a patient lack competence to consent to essential non-psychiatric treatment, a third party may be enabled to make the decision on their behalf. Such third parties or surrogates include: parents on behalf of a minor, persons appointed by legislated bodies pursuant to guardianship legislation, a patient's appointee under a medical power of attorney and a psychiatrist authorised by the relevant Mental Health Act. When medical treatment is required to save a patient's life, to prevent serious damage to a patient's health or to prevent the patient suffering or continuing to suffer significant pain or distress, such action as is necessary can be taken without seeking authorisation from any person. However, should an authorised person be readily available to give consent, good practice suggests that it should be sought.

Factors that will influence whether a third party can or should provide informed consent for a treatment on behalf of another include the imminence of any risk of non-treatment and the severity of the risk of non-treatment. Should a patient's mental condition be temporary and a proposed gynaecological treatment not essential or not an emergency, a decision to proceed with treatment should be delayed until the patient regains capacity. However, should it be deemed that a treatment is essential and urgent, or that a patient's capacity to give informed consent is unlikely to change, then authority to proceed with treatment should be sought from the appropriate third party or surrogate. A distinction needs to be made between essential and urgent treatment and elective or non-essential treatment.

Further reading

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Should women consent to labour?

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The NSW Department of Health is clear in its documentation for consent:

> As a general rule, no operation, procedure or treatment may be undertaken without the consent of the patient, if the patient is a competent adult. Adequately informing patients and obtaining consent in regard to an operation, procedure or treatment is both a specific legal requirement and an accepted part of good medical practice... Failure to (obtain consent) could result in legal action for assault and battery against a practitioner who performs the procedure.
>
> The obligation to obtain consent is distinct from the obligation to disclose information to a patient and warn a patient of material risks. As a rule, all patients have a choice as to whether or not to undergo a proposed procedure, operation or treatment. While a patient might consent to a procedure once he or she has been informed in broad terms of the nature of the procedure, this consent will not amount to the exercise of choice unless it is made based on relevant information and advice. Patients must also be provided with sufficient information about the condition, investigation options, treatment options, benefits, possible adverse effects or complications, and the likely result if treatment is not undertaken, in order to be able to make their own decision about undergoing an operation, procedure or treatment.
>
> A medical practitioner has a legal duty to warn a patient of a material risk inherent in the proposed treatment. Failure to do this may be a breach of the practitioner's duty of care to the patient and could give rise to legal action for negligence. Patients have a legal right to refuse treatment. Consent of the patient is therefore required to be obtained in nearly all cases.[1]

Obstetric care is unique in terms of medical and social expectations. The course of pregnancy, labour and vaginal delivery is considered 'natural', and interference with this 'natural progression' is viewed as an intervention.

We are not aware of what is happening elsewhere in Australia, but in our home state, NSW Health has produced a rather remarkable document titled Towards Normal Birth in NSW, (see boxed extract), which espouses the following themes:

- the promotion of birth as a natural event for most women;
- the need to minimise fear, particularly women's fear, and improve support throughout labour and birth;
- the importance of consistent and balanced information for women and healthcare providers regarding vaginal birth after caesarean section (VBAC) and the potential risks associated with elective caesarean; and
- the need to develop programs of care, both midwifery and medical, that focus on providing continuity of care.

The document does not address the potential risks of labour and normal birth, and while a consent process is mandatory for caesarean section, there is no suggestion that this is required before a woman embarks upon labour. The document refers to the 'potential risk' of elective caesarean section, but does not appear to specifically mention the risks associated with VBAC.

The NSW Department of Health is explicit in its requirements around 'normal delivery':

> Written consent is not required for a normal delivery. Should an operation such as a caesarean section or a blood transfusion be required, the consent process as detailed should be completed, insofar as it is practicable to do so in the circumstances. If implied or oral consent is given to a particular procedure, (such as the use of forceps) this should be noted in the patient's medical record. Discussions about alternatives and material risks should be documented in the record. It may be appropriate for practitioners to discuss these additional procedures during the term of the pregnancy.[1]

To this end, caesarean section requires the written consent of the patient, whereas for the initiation of labour, management of labour and vaginal interventions for birth (for example, instrumental delivery and episiotomy) 'implied consent' is considered adequate. However, few would dispute that the course of labour involves inherent risk that may be material to the patient. This article concerns itself with the obstetrician's duty of care to inform the patient of the risks involved. In particular, birth presents an alternative, that is, caesarean section.

Obstetric care is further complicated by the presence of two patients. By legal definition, the fetus does not have independent rights, although once born, as a separate entity, the child can claim that actions by others may have influenced a negative outcome. The interests of the fetus (or the subsequent neonate) may compete directly with the needs or wishes of the mother. The law is unequivocal in its recognition of the physician's primary responsibility to the mother.

While there are specific risks associated with elective caesarean section, particularly in terms of future pregnancies, it appears inadequate to avoid discussion of the risks associated with labour and vaginal delivery. Even if one limited the discussion to the risk and consequences of perineal trauma, surely it is incumbent on the obstetrician to attempt to convey the material risk of urinary incontinence, anal sphincter injury, uterovaginal prolapse and sexual dysfunction to a patient planning a labour and vaginal delivery. Furthermore, the incidence of post-traumatic stress disorder, perinatal anxiety and depression, difficulty breastfeeding and impaired maternal-child bonding has been linked to a negative birth experience.

Fascinatingly, NSW Health insists on consent for major medical treatments. Examples relevant to obstetrics and gynaecology include:[1]

- any treatment that involves the administration of a long-acting injectable hormonal substance for the purpose of contraception or menstrual regulation
- any treatment that involves the administration of a general anesthetic or other sedation
- any treatment used for the purpose of eliminating menstruation
- any treatment that involves a substantial risk to the patient (that is, risk that amounts to more than a mere possibility) of: (a) death; or (b) brain damage; or (c) paralysis; or (d) permanent loss of function of any organ or limb; or (e) permanent and disfiguring scarring; or (f) exacerbation of the conditions being treated; or (g) an unusually prolonged period of recovery; or (h) a detrimental change of personality; or (i) a high level of pain and stress

It is of interest to note that in NSW, a consent form is required before administration of anti-D to a pregnant woman can be undertaken, in circumstances where long-term data demonstrates great efficacy and safety with this product, but 'written consent is not required for a normal delivery'.[1]

Obstetric care often (not always) offers multiple opportunities for informative discussion. The National Health & Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research, 2007 advises, 'Respect for human beings involves giving due scope to people's capacity to make their own decisions'.[2] While outcomes are not always predictable, many obstetric outcomes are foreseeable. Indeed, the outcome for elective caesarean section, for example, is fairly standardised.

The debate about how women should be cared for in pregnancy, labour and birth will continue. However, recognition of the woman's autonomy, right to be informed and right to informed choice should be paramount and amounts simply to fair, reasonable and ethical care. In the normal course of obstetric care, we suggest that women should formally consent to labour and vaginal delivery.

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NSW Health's policy for the provision of information to patients[1]

Consent is required for a surgical procedure such as caesarean section, because of the inherent risks, both immediate and future. Labour and vaginal delivery, too, carries inherent physical and psychological risk. In standard clinical practice understanding of those risks is assumed. However, we would argue that this is unreasonable. A woman with no prior experience of birth cannot reasonably be expected to have an understanding of the potential pain, fatigue, risk of emergency caesarean section, risk of perineal trauma or risk of postpartum haemorrhage.

The NHMRC in 1993 produced a set of guidelines for medical practitioners on providing information to patients which is largely in accord with the findings in Rogers V. Whitaker.

The NHMRC recommends that practitioners discuss:
(i) the possible or likely nature of the illness;
(ii) the proposed approach to investigation and treatment including:
- what the proposed approach entails,
- the expected benefits;
- common side effects and material risks;
- whether the procedure is conventional or experimental; and
- who will undertake the intervention.
(iii) other options for diagnosis and treatment;
(iv) the degree of uncertainty of the diagnosis and any therapeutic outcome;
(v) the likely outcome of not having the diagnostic procedure or treatment, or of not having any procedure or treatment at all;
(vi) any significant long term physical, emotional, mental, social, sexual, or other outcome which may be associated with the proposed intervention; and
(vii) the time and cost involved including any out of pocket expenses.

The NHMRC guidelines note that a practitioner's judgment about how to convey risks will be influenced by a number of factors. These include: the seriousness of the patient's condition, the nature of the intervention (complex interventions require more information); the likelihood of harm and the degree of possible harm; the questions asked by the patient; the patient's temperament, attitude and level of understanding (including literacy and intelligence level); and accepted medical practice. Information should be provided in a form and manner which helps patients to understand the problem and the treatment options available, and which is appropriate to the patient's circumstances.

Participation in novel treatments and procedures

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Louis Washansky was a 55-year-old Cape Town grocer, who in December 1967, received the world's first transplanted heart. He survived 18 days before succumbing to pneumonia secondary to immunosuppressive drugs. His surgeon, Christiaan Barnard, became a household name and Barnard's desire to be the first to perform a potentially life-saving operation is easy to understand. But what of Louis Washansky's motivation to become the first patient? He cannot have been in any doubt that his risk of not waking up was great. By Barnard's later account, Washansky felt that he had nothing to lose, 'for a dying man it is not a difficult decision because he knows he is at the end. If a lion chases you to the bank of a river filled with crocodiles, you will leap into the water, convinced you have a chance to swim to the other side. But you would not accept such odds if there were no lion.'[1]

While there are notable historical exceptions, the progress of medical treatment relies on patients who are willing to be the first to take the step and participate in trials of new treatments. To a great extent, the expectation that new treatments are developed within an ethical framework is somewhat of a recent development and one that is continually under review. While the history of medicine is filled with tales of maverick individuals making momentous discoveries, the flipside is the isolated practitioner drifting ever further from the mainstream. On the one hand, there is Ignaz Semmelweiss and antisepsis; on the other, there is Chelmsford Private Hospital and deep sleep therapy. Consequently, the conduct of research into novel treatments, including consent for participation in research, is now closely regulated.

For many doctors, our experience with consent involves patients receiving treatments that are tried and tested. While there are risks and benefits to these treatments, we are familiar with them. In many cases we can provide written information outlining them to our patients, with RANZCOG providing many useful resources for this interaction. We can often provide local or personal audit data further informing the patient of their potential outcomes, and patients have the ability to seek out independent data sources if they desire. In most cases, we can be confident that our patients have the ability to obtain a reasonable understanding of the proposed course of treatment before deciding whether to go ahead with it.

In the case of novel or experimental treatments, knowledge of the risks and benefits is necessarily less certain and processes must be in place to ensure participants are as well informed as possible before agreeing to participate in these studies. In Australia and New Zealand, the provision of adequate processes lies with need for ethical approval before a practitioner can embark on innovative treatments. All workers in these countries who wish to provide novel treatments will have access to Human Research Ethics Committees (HRECs) through their hospital, university or other organisation. The National Health and Medical Research Council (NHMRC) in

Table 1. Pathway of clinical trial phases.

Phase I	First administration of the medicine to humans. Medicines are usually given to small numbers of healthy volunteers, but sometimes to people affected by the disease the medicine is intended to treat. The purpose may be to determine the medicine's safety, pharmacokinetics, pharmacological activity, side effects, preferred routes of administration or appropriate doses (for later studies). The studies are usually undertaken in centres equipped for specialised monitoring and a high degree of surveillance.
Phase II	Typically the first trials of the medicine in people with the health condition for which the medicine is intended. The principal aims are to determine efficacy and safety and establish an appropriate dosing regimen. These studies are undertaken in a small number of closely supervised patients and conducted by researchers regarded as specialists in the health condition and its treatment.
Phase III	Undertaken if the Phase II studies indicate the medicine has potential benefits that outweigh any hazards. The studies involve greater numbers of patients with the health condition under study and aim to determine whether the medicine confers clinical benefit in that health condition and whether the incidence and nature of adverse effects are acceptable.
Phase IV	Undertaken after the medicine has been approved for marketing for the treatment of a particular disease or for a particular indication.

Australia is responsible for accrediting HRECs and lists more than 200 associated with government and private organisations.[2]

RANZCOG, in its Code of Ethical Practice, specifically prescribes that: 'Where patients are to be approached to consider participation in research, doctors should: ensure that the research has been properly approved by a human research ethics committee.'[3]

In the case of drug treatments, there is a well-defined pathway of clinical trial phases that provide context to the risk/benefit balance of a particular study.[4] (See Table 1.)

In the development of drug trials, consent is part of a larger, regulated framework and protocols are agreed upon when the trial is registered. Trials of devices may also follow similar phases, while surgical technique developments may not always be introduced in this way.

While there are common considerations in consenting patients for any clinical procedure, there are particular factors in consent for experimental procedures.

Availability of alternative treatments, including the option to not treat at all

In many cases, our patients are not in the position of Louis Warshansky, the lion has not chased them to the river's edge and they may have the option of other treatments. Conversely, if the existing treatments were flawless, then we would not be considering alternatives. It is important that patients are made aware of alternatives to the experimental treatment, especially if effective treatments already exist.

Expectation of success

Patients should be provided with evidence supporting the rationale behind a proposed treatment. This evidence could include results from animal research, earlier studies of similar treatments or in the case of surgery, a discussion of the anatomical rationale for the proposed surgery.

Expectation of risks

Experimental treatments vary widely in their possible risks. Compared to established treatments, experimental treatments have a greater potential for unforeseen adverse outcomes, both in the short and long term. While this need not preclude the development of novel treatments, researchers should be careful to inform potential participants of these outcomes, including that they may not necessarily be reversible. A salient case in gynaecology is in the unexpected short- and long-term adverse outcomes suffered by some women receiving pelvic mesh surgery, and whether women were adequately informed of these risks prior to surgery. These cases include some women enrolled in approved clinical trials, and other women receiving the procedures as part of normal clinical care, presumably with consent procedures reflecting both these settings.

Possible conflicts in being both the clinician and researcher

Clinical research spans the range from multi-centre randomised trials where researchers may recruit patients into the trial but are at arm's length from allocation to treatments and measurement of outcomes, to small local studies where a single clinician may recruit participants, perform the intervention and conduct evaluation. In some cases, a researcher may enrol their own patients in a trial of a new therapeutic technique of their own design. This can lead to a conflict between a desire to help patients by providing them with the latest, hopefully more effective, treatments, and the expectation that patients should have the final choice on whether to proceed with an experimental treatment. On the patient's part, their decision to consent to a novel treatment may be influenced by a desire to please their treating doctor with whom they may have built up a therapeutic relationship, by agreeing to take part in their trial. This situation risks violating the principle that participation in a trial be truly voluntary. Because of this potential conflict of interest, the NHMRC suggests that 'where the researcher is also the treating health professional, it should be considered whether an independent person should seek the consent of potential participants.'[4]

In conclusion, while sharing many of the concepts of consent for any medical procedure or treatment, consent for new or experimental procedures does have additional considerations. Clinicians and researchers need to be aware of these differences and incorporate them in to their practice. In many cases novel procedures should be conducted with the approval of a HREC, with appropriate recruitment and consent forming part of the approval process.

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Blurred lines: a doctor practising in the family

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In an obstetrician's career, tragic unexpected outcomes are, sadly, part of everyday practice. However, being present when a family member is affected by a tragedy, such as the loss of a pregnancy, is the reality you never want to face. In this situation, we face the blurred lines of what our role is – clinician or relative? – and the issues surrounding patient consent are made more complicated.

It is Saturday night. I am driving to a night shift when my brother calls. Something is not right. He tells me the symptoms his wife, who is 22 weeks pregnant, is having. I tell him to meet me at the hospital immediately. The drive is long. The whole time my brain assesses probabilities – my eyes water and my chest hurts. All I want is for everything to be okay. All I want is for my gut instinct to be wrong. As I enter the birthing room they both look up, silent desperation paints their faces. The midwife is trying to find a heartbeat; the silence is too hard to bear.

An ultrasound scanner sits in the corner. The private obstetrician is still 40 minutes away. They see me glance at it. The worry etched on their faces begs me to perform the scan. I do. Any hope there was is now gone.

The role of a doctor

Historically, the doctor's role has been defined by the Hippocratic Oath. Doctors should act in the best interests of their patient, accept responsibility, develop a trusting relationship with the patient and display professional commitment. On the other hand, the role of a family member is to love and protect, be able to communicate and comfort without words, and to offer support through the good times and the bad.

When these roles become intertwined, it can be a challenging experience for us as doctors: the emotional investment in your family versus the diagnostic capabilities of your mind. The natural instinct is to jump in, find a diagnosis and cure the sick; yet when we find ourselves in a scenario like this, should we learn to take a step back and let another doctor take over that role?

Doctors have always been discouraged from providing medical care for family members, dating back to ethical principles from the early 1800s that argued for the separation of professional and personal identities in the care of family members.[1] Reasons for this stem from the emotional distraction related to the patient as family member that can cloud one's decision-making, critical thinking and sound judgment.[1] The consent process itself can also be tricky; withholding details in order to protect the ones you love.

From experience, dissociating oneself from a loved one who is in a grave medical situation can be difficult. Physicians have recognised that, at times, it is not feasible to keep their personal and professional lives separate; indeed, it is morally impossible.[1] One feels compelled to be involved and carry out whatever task is needed solely to care for a family member, blind to the risks at stake.

From the family member's point of view, it can be an overwhelming relief to be treated by a familiar and loving face; a person they trust and understand.[1] The attention to detail, empathy and thoughtfulness of a loved one is in stark contrast to a stranger's care, no matter how well-qualified and professional the practitioner may be.

Finding the balance between your internal identity and responsibility versus the external influences of family and profession can be hard. Nothing can truly prepare you in your career for simultaneously being a concerned family member and a person who has a position of responsibility.[1]

Implied consent

To obtain consent is not only a mandatory legal requirement, but also a part of good medical practice for any operation, procedure or treatment administered to a patient.[2] Consent can be implied in certain situations, where the patient shows their agreement through their actions or by complying with instructions.[3] As doctors, however, we should take particular care when relying on implied consent, as in some cases there can be misunderstandings if construed the wrong way. In an obstetric setting, interpreting implied consent can be as simple as performing an abdominal palpation on a smiling antenatal patient; however, in the case of an adverse outcome, it can be far more complex.

When doctors face delivering news of an undesirable diagnosis, we are expected to interpret a patient's body language and then act in response to it. We provide the sad news, the appropriate facts, tailor the quantity of information and predict the consequences the results will have. Consent is said to be valid if the patient has the capacity, the correct information and acts voluntarily, but fulfilling these requirements in a split second of momentary decision-making is far easier said than done. Furthermore, the patient's capacity at the time to make clear decisions, especially as relayed by body language, is questionable.

Breaking bad news

Breaking bad news is a task many doctors have to perform daily, yet its importance

is often undervalued.[4] It requires skilful communication, the strength to be honest and the ability to remain calm while conversing.[5] These traits, in addition to tailoring the amount of medical information given to a patient's capacity to absorb, are all necessary in order to achieve good outcomes.[5] One must find the ideal setting, use the appropriate vocabulary, body language and express words in an empathetic way, which in an obstetric setting can be particularly challenging, given the contrast to the joy that usually surrounds a healthy pregnancy.[5,6]

These encounters and the patient's responses are unpredictable and, quite naturally, involve an immense range of emotions.[4] The degree of distress the conversation induces can also be heart-breaking for the medical professional. Doctors describe it as one of the most difficult tasks they engage in clinically and some report immense levels of stress, fear and anxiety.[5] In extreme cases, this can have an adverse impact on their clinical and communication performance, and affect the clinician both physiologically and psychologically.[5]

Some doctors feel the only way to protect themselves in these situations is by forming a barrier between themselves and the patient. However, when breaking bad news to a family member these tactics disintegrate. To be honest and direct with a family member requires even greater reserves of strength, and delivering news of a poor prognosis is almost impossible. In these settings, it is the empathy that gets you through, using your emotional connection and not logic.

The aftermath

Returning to work after a family tragedy is one of the final tasks to be accomplished. Some find the strength by seeing it as a rewarding life experience, but others find it mentally draining and rely on external assistance to ease them slowly back on to the right track.[7]

Either way, we must recognise that the physician-relative scenario is a unique one: stressful, emotional and challenging. The flashbacks that can occur for the remainder of your career have the ability to catch you off guard and you must look after yourself accordingly. Whether this final step involves counselling or confiding in a mentor, it is important to communicate your feelings and have a plan for the aftermath as you move forward.[8]

To this day, I still question my actions of that evening. Did I do the right thing? Did I interpret the implied consent correctly? Should I have played the role of a sister, ignored my medical professional instincts, and just joined them in desperate waiting while the events unfolded? Or would that have provided false hope and merely delayed telling them the inevitable?

Doctors will always be family members and the value of our emotional attachments should not be dismissed, but we should be made more aware of these conflicting expectations and the challenges that may arise from being the doctor in the family.

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Q&a

For the broader *O&G Magazine* readership, balanced answers to those curly-yet-common questions in obstetrics and gynaecology.

Q *'A 36-year-old primigravida is fully dilated and has been pushing for three hours, with no descent of the fetal head. Despite sound obstetric advice and explanation, she steadfastly refuses caesarean section. Where does one legally stand in such circumstances?*

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a Situations such as this are always difficult to deal with for doctors, particularly since the legal position is not completely clear. Australian courts have not yet had to rule on a woman's right to refuse a caesarean section (CS), and each patient's circumstances are of course different.

There are, however, several English cases that have confirmed that women of 'sound mind' have this right even if the refusal is likely to result in the death of the woman and/or her unborn baby. By contrast, the decisions in the United States have divided across state lines, with some states taking the same approach as England, while others have ordered that a woman undergo a CS to save the life of the unborn baby. Were the issue to come before the Australian courts, we consider that the English approach is likely to be adopted; both countries do not recognise the fetus as a separate person, and therefore the rights of the mother will be upheld.

Presumption of capacity

In the English case of Re MB,[1] a patient refused a CS because she had a needle phobia. The Court of Appeal considered her right to refuse treatment and provided the following guidance:

1. 'Every person is presumed to have the capacity to consent to or to refuse medical treatment unless and until that presumption is rebutted.
2. A competent woman who has the capacity to decide may, for religious reasons, other reasons, for rational or irrational reasons or for no reason at all, choose not to have medical intervention, even though the consequence may be the death or serious handicap of the child she bears, or her own death. In that event the courts do not have the jurisdiction to declare medical intervention lawful and the question of her own best interests, objectively considered, does not arise.'[1]

The English cases[2] formed the basis of the guidelines issued by the Royal College of Obstetricians and Gynaecologists[3] that state:

> The first question is whether the patient has capacity to consent to, or to refuse, treatment and is refusing recommended treatment. If the patient has capacity there is no action to be taken save for the making of meticulous notes.

Determining lack of capacity

A person lacks capacity if: 'some impairment or disturbance of mental functioning renders the person unable to make a decision whether to consent to or to refuse treatment.'[1] Patients may have a temporarily reduced capacity at the time when the decision has to be made. This could be due to a compulsive disorder or phobia (such as the needle phobia in Re MB). It could also be due to confusion, shock, fatigue, pain or drugs or fear that operates to 'paralyse the will and thus destroy the capacity to make a decision'.[4] However, the courts have emphasised that in these situations doctors must be satisfied that 'such factors are operating to such a degree that the ability to decide is absent'.[1]

The recent NSW case of Re a patient Fay[5] considered different facts, but provides useful judicial guidance. The NSW Supreme Court was required to assess the capacity of a young woman to refuse a termination of her 22-week pregnancy in circumstances where continuation of the pregnancy was likely to result in serious injury to her health or her death. The court held that a person will be seen as lacking capacity if they are:

- unable to comprehend and/or retain information that is material to the relevant decision, in particular the consequences of the decision; or
- they are unable to use and weight the information as part of the process of making the decision.

Impact of advice on decision-making

It has been recognised that patients are entitled to receive advice and assistance from others in reaching a decision, especially from family members, so long as it does not 'overbear the independence of the patient's decision'.[4] In a situation where there is a dominant family member who appears to be unduly influencing the patient's decision, you should seek input from a psychiatrist regarding the patient's capacity, whether or not they are being influenced by someone else and also practical advice about managing the patient's family, as appropriate. Legal

advice may also be required to determine the options for addressing these difficult clinical circumstances.

Advice on the risks of refusal

Once a decision has been made that the patient has capacity to refuse treatment and she is not unduly influenced by anyone else, it is critical that she and her partner or close support person are fully aware of the potential consequences to the patient and her unborn baby by refusing a CS. You may wish to involve an obstetric colleague to provide a second opinion.

In particular, it should be explained what clinical steps will need to be taken in order to deliver the baby if the head does not descend. Such advice may include the different options for delivery methods depending on the level to which the fetal head descends, the condition of the fetus at each relevant time, as well as treatment options for delivery if the fetus does not survive. The advice given should be well documented in the medical records.

To ensure this information is properly understood, it is advisable to consider involving a social worker, psychiatrist or the patient's GP if there is sufficient time to arrange this. If there are any language barriers to the patient understanding your advice, you should also involve an interpreter, preferably an independent one. It would also be prudent, and is sometimes required by internal policy, to escalate the matter to hospital management to, for example, the medical director or CEO, depending on the management structure in place at your hospital.

Antenatal care

It may be easier to address these difficult issues if you have had the opportunity to discuss them with the patient during antenatal visits. It is good practice to review a patient's birth plan with them at that time. This can provide an opportunity for discussion about the treatment options if, for example, a patient expresses a firm view against a CS. The patient's partner or other support person can be involved in the discussion.

If the patient tells you her particular wishes about escalation of treatment, it is important to document these in the medical records, together with discussion and advice given at that time. Consider also the benefit of consulting your colleagues at that time, either for a second obstetric opinion or from other specialities as part of a multi-disciplinary approach.

Change of mind

While a patient may have initially steadfastly refused to have an operation, she may change her mind as the labour continues. It is important to let her and her support person know that she can opt for the CS at a later stage, provided that it is still clinically feasible.

In our experience, once the potential consequences are clearly explained, most women do change their mind and agree to a CS with a safe delivery of their baby. Further advice should be sought from the hospital's lawyers and/or your Medical Director if you are in any doubt as to the patient's capacity to refuse treatment, as it may be necessary to obtain an urgent court order to determine capacity.

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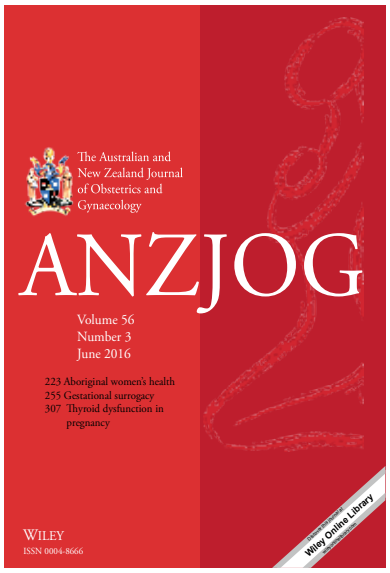
FROM THE EDITOR'S DESK

Welcome to our regular page of highlights from the RANZCOG peer-reviewed academic journal, *ANZJOG*.



First up is the news that the 2015 Journal Citation Reports[1] were released in June and I am very pleased to report that *ANZJOG*'s 2015 Impact Factor is 1.738 – an increase to the 1.510 Impact Factor of 2014. The journal's ranking in the Obstetrics and Gynaecology category is 43/80. This excellent increase was achieved under the editorship of my predecessor, Prof Jan Dickinson; the Associate Editors and I extend our congratulations to her.

We are sorry to announce that Dr Gerry Wain, who is retiring from gynaecological oncology practice, is also retiring from the Editorial Board, though we wish him a long and enjoyable retirement. Gerry has served as Associate Editor in his specialty since 2010, and has made a huge contribution to the journal in this area.

The June issue of *ANZJOG* has a section devoted to Aboriginal and Torres Strait Islander women's health, with a guest editorial from Profs Jacqueline Boyle and Sandra Eades, and four original contributions. Our guest editors, who have enormous experience in the area of Indigenous women's health, conclude that there have been improvements at all levels of healthcare, but that inequalities persist, and 'the reasons for these inequalities are complex'.[2] They make a number of suggestions for how better outcomes might be achieved.

A study by Whish-Wilson et al[3] of urban Victorian Indigenous women attending a Melbourne hospital for pregnancy care shows similar outcomes to non-Indigenous women with regard to low birthweight and preterm birth, and the incidence of diabetes in pregnancy was lower among Indigenous women attending for antenatal care than among non-Indigenous. However, smoking in pregnancy and obesity remain major problems for Indigenous women in this cohort. From Western Australia (WA) Diouf et al[4] also report high levels of smoking among Indigenous women who attended for antenatal and intrapartum care across the state in 1986–2009, a higher incidence of diabetes in pregnancy, and higher risks of stillbirth, neonatal death and preterm birth than among non-Indigenous women, although there was an encouraging trend towards fewer teenage pregnancies and lower incidences of pre-eclampsia and antepartum haemorrhage. Also from WA, Bower et al[5] report on the impact of the introduction of folate fortification of flour for bread-making on the red cell folate levels of a cohort of Aboriginal women and men, finding that levels have risen since a similar pre-fortification study. All participants reported eating shop-bought fortified bread at least once a week, and no participant was folate-deficient in the current study. The authors also report a 68 per cent decline in the incidence of neural tube defects as recorded in the WA Register of Developmental Anomalies, an impressive result.

Finally, among articles on Indigenous women's health, Kandasamy et al[6], in an opinion piece, note that stillbirth (SB) rates have remained unchanged across Australia over the past decade and that figures for Indigenous births are twice those of non-Indigenous. Fetal autopsy is essential to determining possibly preventable causes of SB and the authors believe there is a need to identify both facilitators and barriers to obtaining consent for autopsy from Indigenous women and their families, in a culturally safe and appropriate manner, if progress is to be made in this area.

Submissions to *ANZJOG* in recent months have trended strongly towards obstetric topics rather than gynaecological, and this can be seen in this issue by the number of obstetric Original Manuscripts – ten plus three in the Indigenous health section, versus one gynaecological. Topics covered in the obstetric articles include thyroid dysfunction in pregnancy,[7] outcomes for MCDA twins following laser therapy for twin-to-twin transfusion syndrome,[8] the mixed and sometimes inaccurate information being given by professionals to the parents

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of extremely preterm babies[9] and an interesting article on gestational surrogacy.[10]

Our one gynaecological Original Manuscript describes a case series of women with spontaneous regression of vulval intraepithelial neoplasia[11] and a Short Communication looks at micronised progesterone for menopausal hormonal therapy.[12] There is also a thoughtful review on a gynaecological topic: the controversy surrounding the use of dexamethasone for the prevention of female virilisation in congenital adrenal hyperplasia.[13]

I have also instituted a new section, Sexual and Reproductive Health, with the inaugural article describing variations in the post-abortion initiation of long-acting reversible contraception in a cohort of New Zealand women.[14]

The August issue of *ANZJOG* will include five articles on the subject of diabetes and pregnancy, a topic on which we are currently receiving a large number of submissions. We will also return to a more balanced number of a variety of gynaecological topics.

I am very pleased to report that *ANZJOG*'s 2015 Impact Factor is 1.738 – an increase to the 1.510 Impact Factor of 2014.

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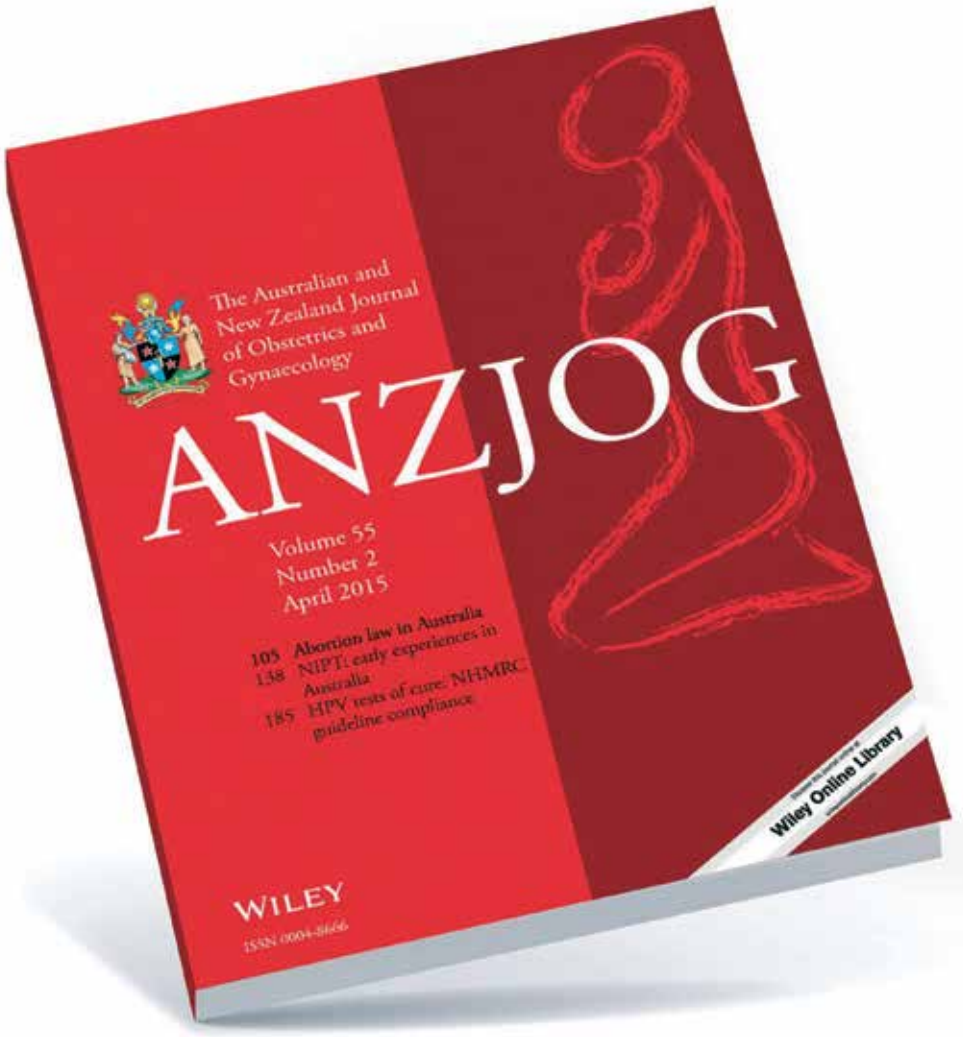

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Journal Club

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

Ovarian-sparing hysterectomy and ovarian reserve

It is common to preserve the ovaries in premenopausal women having hysterectomy for benign conditions. Despite this, a number of previous studies have demonstrated that women who have received ovary-preserving hysterectomies have earlier menopause than women who have not had hysterectomy. Trabuco et al report the findings of prospective study of anti-Mullerian hormone (AMH), a marker of ovarian reserve levels, in 148 premenopausal women receiving ovary-sparing hysterectomy for benign conditions compared with a referent group of 72 women of the same age with intact reproductive organs. AMH levels were measured at baseline prior to surgery and one year later. The results showed that while there were no differences in AMH level between the two groups at baseline, women who received ovary-sparing hysterectomy had a significantly greater percentage decrease in AMH levels (40.7 per cent decrease compared with 20.9 per cent; P=001) and were more likely to have non-detectable levels (12.8 per cent compared with 4.7 per cent; P=5.02) at the one-year follow-up compared to the referent group. The authors hypothesise that the decrease in ovarian function following hysterectomy may be due to a disruption of ovarian blood flow due to hysterectomy, or a removal of endometrial endocrine or paracrine influences on the ovaries resulting in a loss of ovarian function.

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HHV-6A virus and infertility

Human herpes virus (HHV)-6A was first discovered in 1986 and has been implicated in conditions such as liver disease, pneumonitis, myocarditis and multiple sclerosis. HHV-6A has also been identified in the genital tract and this study sought to determine if there were differences in the distribution of HHV-6A in fertile and infertile women. The study included 30 women with unexplained primary infertility, and compared them to 30 women with at least one previous successful pregnancy. There were no significant differences between the two groups in age, duration of menstrual cycle, and hormones, including FSH, LH and progesterone. Biological samples were taken at the same day of the menstrual cycle and both groups were analysed for the presence of HHV-6A in endometrial biopsies and in peripheral blood. The results showed that while the percentages of women with HHV-6A in peripheral blood cells were similar in infertile (27 per cent) and fertile (28 per cent) women, 43 per cent of women in the infertile group had HHV-6A DNA in their endometrial biopsies compared to no women in the fertile group. While this is a small study, this result is striking and is sure to be the focus of future research.

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CIN in pregnancy

It is estimated that the prevalence of cervical intraepithelial neoplasia (CIN) in pregnancy is about one per cent. Once invasive cancer has been excluded, the current practice with CIN in pregnancy is careful observation with smears, colposcopy and, if necessary, colposcopically guided biopsy. This retrospective study analysed all women presenting to an Austrian colposcopy clinic between 2005 and 2010. Within the study period, the authors identified 51 pregnant women with histologically proven CIN. At the first biopsy in pregnancy, they found CIN I in 33 per cent, CIN II in 14 per cent and CIN III in 53 per cent of the women included in the study. The mean gestational age at diagnosis was 15 weeks. During the same period, they identified a control group of 51 consecutive non-pregnant women, which was matched by CIN grade at diagnosis and compared the progress of CIN in both groups. In pregnant women, examinations including Pap smear and colposcopy with or without biopsy were performed in each pregnancy trimester and eight weeks postpartum. Non-pregnant women with CIN were seen every 3–6 months and examined with colposcopy and biopsy.The postpartum evaluation of the pregnant group revealed a significantly higher tendency to spontaneous regression of CIN (57 vs 31 per cent, p=0.010) and a higher complete remission rate (41 vs 28 per cent, p=0.144) when compared to the non-pregnant group. There was also a significantly lower rate of persistence of CIN in the pregnant compared to the non-pregnant group (39 per cent vs 59 per cent), and a lower rate of disease progression (four per cent vs ten per cent). The authors conclude that careful observation of CIN in pregnancy is safe and that there is a relatively high probability of disease regression, with only a small risk of progression to higher grade disease.

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Case reports

A rare case of *Enterobius vermicularis* causing pelvic inflammatory disease

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Pelvic inflammatory disease (PID) is a common condition that causes acute abdominal pain in women. The disease generally involves inflammation of the fallopian tubes, endometrium, pelvic peritoneum and contiguous structures.[1] While *Neisseria gonorrhoeae* and *Chlamydia trachomatis* are frequent causes of PID, there are other pathogens, such as *E. coli* and *Mycobacterium tuberculosis,* that less commonly cause PID.[2]

Enterobius vermicularis is a nematode that predominantly infects the human small and large intestines.[3] Rarely, its extraintestinal infestation has been reported.[4] This case presented is of an 11-year-old girl with acute lower abdominal pain, who was initially treated with the working diagnosis of acute appendicitis. However, intraoperatively, findings were suggestive of PID, with histopathology confirming *Enterobius vermicularis*. Therefore, it is important that clinicians are aware of the possibility of *Enterobius vermicularis* causing PID in children.

PID is an inflammation of the female reproductive tract, commonly a sequela of an infection. This infection can involve the vagina and cervix and may also progress to include the fallopian tubes and ovaries.[2,5] Patients can present with a wide range of clinical manifestations, most commonly acute lower abdominal pain. If untreated, in the long term this disease can lead to infertility,[5] ectopic pregnancies and chronic pelvic pain.[2] Therefore, diagnosis and early treatment are important.

PID is associated with symptoms of acute lower abdominal pain of varying intensity, abnormal vaginal discharge, dyspareunia and postcoital bleeding. Even though systemic features are not common in PID, patients can report experiencing fevers, chills and nausea. Clinically, PID can be demonstrated with cervical tenderness and adnexal tenderness. Endocervical swabs can confirm the pathogen,[7] while the standard for diagnosis of PID remains laparoscopy. The treatment regime for PID is usually a single dose of 500mg azithromycin and 1g ceftriaxone followed by 100mg doxycycline twice daily for two weeks[8] for common pathogens of PID.

Enterobius vermicularis mainly infests the large and small intestine, where it completes its entire lifecycle.[5] Once the ova are transferred to the lumen of the gastrointestinal tract, the protein layer of the ova dissolves and the larvae are released to the small bowel. After mating, the male worms die and the gravid female worm migrates to the perianal region and lays its eggs, causing symptoms of itch and irritation. Reinfection occurs via faecal-oral route, by transfer of the eggs.[11] However, given its low pathogenicity,[12] the infected individual can be asymptomatic or have non-specific symptoms of abdominal pain, nausea and vomiting.[11]

Enterobius vermicularis is not a well-known cause for PID: our literature review found only three reported cases of ectopic infestation,[1,9,10] mainly in the young female upper genital tract. We report one such case in detail.

Case report

An 11-year-old girl was an inter-hospital transfer from a rural town with right iliac fossa (RIF) pain. She presented with a two-day history of crampy RIF pain, which worsened with food, and denied any nausea, vomiting, urinary or bowel symptoms. She did not have any systemic symptoms, such as fever or weight loss. She had not attained puberty. Her past medical history, family history and social history was unremarkable. On examination, all her observations were within normal limits and she was afebrile. The only remarkable finding was tenderness on deep palpation in RIF; however, she was not peritonitic and there was no obvious mass felt.

Laboratory blood tests were generally within normal range; of note, there was a white cell count of 9.6x109/L and the C-reactive protein was less than 2mg/L. The urine sample collected did not culture any bacteria to suggest a urinary tract infection. An ultrasound of the abdomen and pelvis was performed, revealing a central hypo-echoic focus of 29mmx13mmx26mm in the RIF, consistent with infectious or inflammatory phlegmon, suggestive of acute appendicitis.

The decision was made to proceed with laparoscopic appendectomy. Intraoperatively, there was a clump of inflamed omentum, separate from the appendix, which appeared normal. On inspection of the reproductive organs, the fallopian tube and uterus were inflamed with fibrin adhesive deposits, of similar appearance to PID. The omental mass was resected and sent for histopathology analysis. Peritoneal fluid was sent for microbiology, culture and sensitivity.

Postoperatively, the patient was still in pain. On gynaecology and paediatric review, the patient was commenced on treatment for PID, with a high suspicion of sexual abuse. However, sexual abuse was denied by patient and mother.

The culture and microscopy did not reveal any common pathogens that cause PID; however, on day six of hospital admission,

histopathology of the omental resection demonstrated fragments of helminth, suggestive of *Enterobius vermicularis*. Figure 1 shows the microscopic picture of the helminth, with associated inflammatory response. On confirmation from histopathology, the patient was treated with two doses of albendazole 400mg and discharged. Counselling was provided for family regarding treating all family members and general hygiene.

Discussion

Enterobius vermicularis is one of the most common nematodes with low pathogenicity that infects the human body.[3,12] It is more commonly found in temperate regions than in tropical regions. It is predominantly seen in children in the age groups of five to ten years old.[5,13] It usually infests the large and small intestines and ectopic infestation with this species is rare. This case study is a rare presentation of this nematode's ectopic manifestation causing PID.

There have been three cases reported of ectopic *Enterobius vermicularis* infection causing PID in adolescents.[1,9,10] This can occur when the gravid female worm migrates from the perianal area to the vagina, ascending through to the cervix and involve the fallopian tubes and peritoneum. Most infestations are asymptomatic, but can provoke pathologic reactions, giving severe symptoms of cervicitis, endometritis, salpingitis, oophoritis and generalised peritonitis.[5,9] In our case, the initial working diagnosis and management for this young patient was acute appendicitis,[14] which commonly mimics the symptoms of PID. Histopathological and cytological diagnosis[15] is the only way for definitive diagnosis and confirmation of PID owing to *Enterobius vermicularis*. Therefore, early management with anti-parasitic treatment is important. The patient and family must also be well counselled about treatment with anti-parasitic medications for the whole family and practising good hygiene, as poor hygiene is the main source of the spread of infection.[16]

Without treatment, the sequelae to the acute phase of PID is chronic pelvic pain, ectopic pregnancy, tubal infertility and intra-abdominal scarring.[1,17,18] There is a low threshold of diagnosing PID in sexually active young women. It is important to consider rarer causes of PID, such as ectopic manifestations of *Enterobius vermicularis*, in non-sexually active children. Even though the diagnosis of *Enterobius vermicularis* in the female genital tract can be challenging, this case further confirms that the ectopic spread of *Enterobius vermicularis* causing PID is possible.

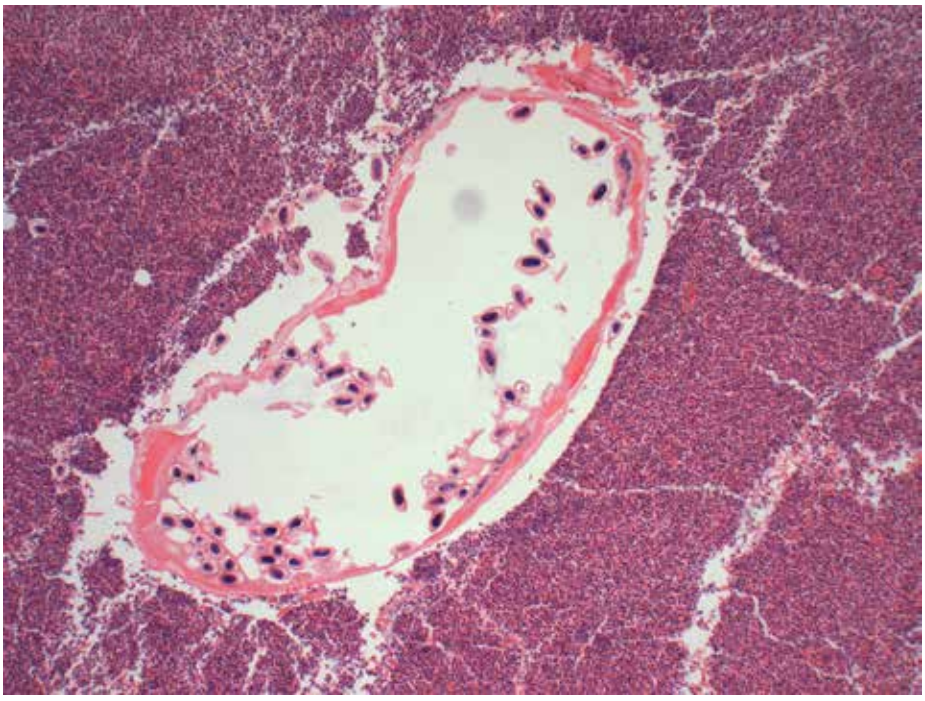

Figure 1. Helminth surrounded by eosinophilic infiltration.

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Ureteric obstruction with a Mirena levonorgestrel intrauterine device

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A 29-year-old woman had the Mirena® levonorgestrel-releasing intrauterine system (LNG-IUS) inserted by her gynaecologist for contraception at four months postpartum. She was breastfeeding and amenorrhoeic at the time.

One year later, her GP was unable to visualise the Mirena strings on speculum examination. The patient thought the Mirena had been expelled spontaneously and was reassured as a pelvic ultrasound did not show sonographic evidence of an intrauterine device (IUD). Her gynaecologist then inserted a copper IUD at her request. The patient experienced left-sided hip pain almost three years later and had the copper IUD removed by her GP. An X-ray of her left hip and pelvis was performed for ongoing pain, and revealed an IUD in the left pelvis. A pelvic ultrasound reported left hydronephrosis and an empty uterine cavity. A subsequent CT scan confirmed left hydronephrosis and hydroureter with obstruction at the level of the mid-pelvis, in close proximity to the displaced IUD.

A laparoscopy performed four days later revealed a fibrous band across the left ureter in the mid-pelvis with proximal gross hydroureter. A Mirena was seen lying next to this stricture band (see Figure 1, Left). There was no laparoscopic evidence of other pelvic pathology or endometriosis. A urologist attended intraoperatively and performed a cystoscopy and retrograde pyelogram, confirming an obstructed distal left ureter (see Figure 1, Right). A left ureteric stent was inserted, dissection of the left lateral pelvic side wall performed, and the stricture excised. The hydroureter was noted to improve immediately after excision of the stricture band. The ureteric stent was removed six weeks later, with an uncomplicated recovery. Histopathology of the excised tissue showed mild peritoneal inflammation with no evidence of endometriosis.

Discussion

The Mirena LNG-IUS obtained TGA approval in 2000[1] and has gained popularity in clinical practice in Australia due to its dual action of contraception and menstrual flow reduction. Almost a million Mirena have since been sold in Australia.[2]

Perforation of the uterus with IUD insertion is uncommon, with a reported incidence of 0.1 per cent.[3,4] Uterine perforation by an IUD can occur at the time of insertion without recognition by the practitioner. In the majority of such cases, the IUD is found lying freely in the pelvis and laparoscopic removal is the first choice of therapy.[3,5] IUD insertion while breastfeeding, or within an interval of less than 36 weeks since last delivery, are associated with a six-fold increase in the risk of uterine perforation.[3] The incidence of serious adverse events is rare.[3] The risks and benefits of IUD insertion in the postpartum period while a woman is breastfeeding should be carefully considered by both clinician and patient.

An English literature search in combination with the manufacturing company of the Mirena (Bayer Australia Limited) did not reveal any reports of a Mirena associated with ureteric obstruction, nor are there any reported cases within Bayer's global pharmacovigilence database.[6] We believe this is the first report of a ureteric complication associated with a misplaced Mirena LNG-IUS.

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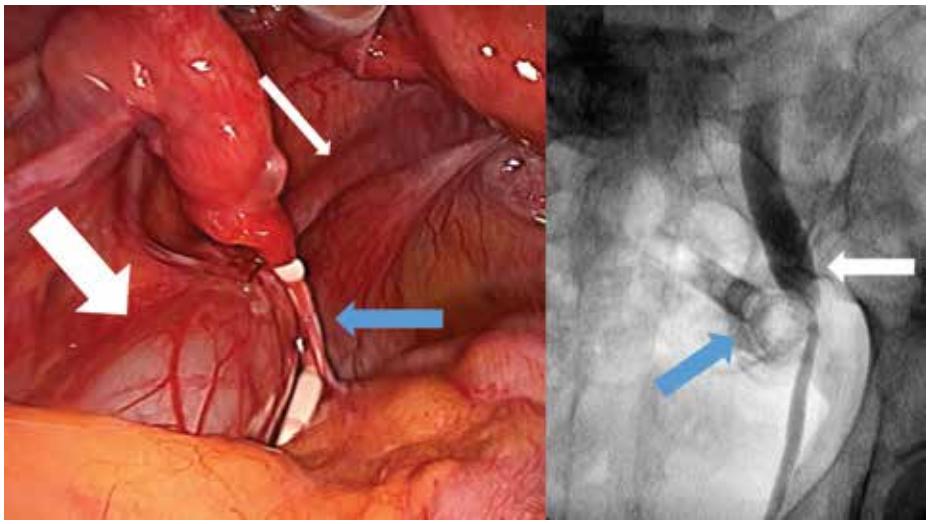

Figure 1. Left: Proximal hydroureter (wide white arrow) is seen with a normal distal ureter (thin white arrow). A Mirena IUD is seen lying at the level of obstruction (blue arrow). Right: Retrograde pyelogram performed in theatre. The Mirena IUD (blue arrow) is visible, along with gross proximal hydroureter (white arrow).

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Sudden unexpected postnatal collapse of a newborn during skin-to-skin time

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The sudden unexpected postnatal collapse (SUPC) of a presumably healthy newborn in the delivery room is uncommon. We report a case of an apparent life-threatening event (ALTE) of a healthy newborn who was in a prone position on her mother's abdomen during early skin-to-skin contact.

Case report

A female infant was born by spontaneous normal vaginal delivery at 40+6 weeks of gestation to a primigravida mother. Mother was a 26 year old whose blood group was O positive, with normal serology and a negative GBS status. There were no other risk factors for infection. The mother's antenatal scans were normal. The baby's birthweight was 4030g. Apgar scores were 9 at one minute, 9 at five minutes, 10 at ten minutes. No resuscitation was needed initially and the baby was given to the mother for skin-to-skin contact.

At 45 minutes of age, the baby was found to be unresponsive, floppy and grey in colour. No heart sounds were heard and the baby was not making any respiratory effort. Intermittent positive pressure ventilation (IPPV) with cardiac compression was commenced by the obstetrician and midwife. The paediatric team arrived within a minute of the incident. Full resuscitation was initiated, including IPPV, cardiac compression, intravenous fluid bolus and antibiotics. At five minutes of resuscitation, as the baby was not making any respiratory effort, endotracheal intubation was initiated. The newborn clinically improved, with a good heart rate and oxygen saturation. After stabilising, the baby was transferred to the special care nursery (SCN).

In the SCN, the baby's oxygen requirement decreased. The baby clinically improved, with good respiratory efforts, and was extubated to high-flow respiratory support within an hour. Throughout the event, the infant maintained normal blood sugar and body temperature. During the stay at SCN, the baby continued to clinically improve, the high-flow support was gradually reduced and, within ten hours of age, the baby was comfortably breathing in air without any respiratory distress. The blood investigations, chest x-ray and head ultrasound scan results were normal. In the SCN, the baby remained clinically stable. There were no dysmporphic features noted and other clinical examination was unremarkable. Enteral feeds were introduced on day two and full-suck feeds on day three. The baby was discharged home on day six of life, with a plan of follow-up appointments in the paediatric outpatient clinic.

Discussion

SUPC or ALTEs in the maternity ward within the first day of life have received increased attention. These events can affect an apparently healthy newborn in the delivery room during the first hours of life, especially during early skin-to-skin contact with the mother. Though ALTEs are rare, the consequences are grave, with death reported in half of the cases and permanent disability in a majority of the surviving infants.

From various studies published, the majority of reported incidents occur within two hours of birth, often at the time of the first breastfeeding attempt or when the infant was in a prone position on his or her mother's abdomen during early skin-to-skin contact. In most cases, the mother was a primigravida.

There are many benefits of early skin-to-skin contact between mother and baby and breastfeeding in the delivery room. However, in view of the risk of ALTE, surveillance of newborns is needed. Perinatal medical personnel (obstetrician-gynaecologists, midwifes, nurses and paediatricians) should be aware of ALTEs and carefully monitor and ensure proper positioning of healthy neonates during this delicate period of mother-infant attachment, in particular for primigravida mothers.

Guidelines for safe postnatal care of infants should include appropriate vigilance of infants, particularly where mothers are primiparous or where their ability to assess the baby may be impaired.

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UGSA: highlights of the 2016 ASM

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The annual scientific meeting (ASM) of the Urogynaecological Society of Australasia (UGSA) was held in New Zealand from March 11–12, in the vibrant city of Auckland. This year's ASM was a well-designed collection of basic science, clinical practice and critical appraisal of the current practice in urogynaecology, preceded by high-powered workshops and concluding with the RANZCOG Trainees' Day. The organising committee invited world-renowned speakers, including Prof John DeLancy, A/Prof Pamela Moalli, Prof Linda Cardozo and Prof Don Wilson.

The conference was attended by 250 delegates; we had 27 podium presentations, two roundtable debates and nine oral abstract presentations by delegates.

In the opening session of the conference, 'Childbirth and the pelvic floor', Prof John DeLancy delivered the first podium presentation, 'Biomechanics of childbirth'. This included pelvic floor birth-related injuries and implications of such injuries in large-scale population figures. Pelvic floor birth injuries are latent; they occur during birth and remain dormant for many years, and may lead to prolapse later in life. Potential causes for prolapse following childbirth injury can arise from three different categories of trauma: muscle compression, denervation and muscle tear. It is important to identify the cause because prevention depends on it. For example, if the cause for levator ani injury is muscle compression, then it can be prevented by shortening the second stage of labour; if the injury is due to muscle tear, then prevention can be achieved by slow and gradual delivery, so that the muscles can accommodate the stretch. Indeed, each of these traumas occur during labour to varying degrees, but the main birth-related injury leading to pelvic organ prolapse is levator ani muscle tear. Miller et al[1] have demonstrated this on serial magnetic resonance imaging of the pelvis at one and seven months after childbirth. De Lancey et al showed the presence of major levator ani defect in 55 per cent of women with pelvic organ prolapse compared with 15 per cent of those without pelvic organ prolapse.[2] Major risk factors for this type of injury are known to be occipito-posterior fetal position and forceps delivery.[3] There was further elaboration on this aspect of birth injury by Prof Peter Dietz; he has revealed the magnitude of the impact of forceps delivery on levator ani muscle tear in several studies.[4-5]

Another outstanding aspect of the meeting was the presentation by Prof Don Wilson on the URCHOICE trial.[6] URCHOICE is a scoring system developed from long-term prospectively collected data of women, 12 and 20 years from the birth of their child. URCHOICE is an acronym that takes in to account the important risk factors in pelvic floor dysfunction (PFD):

Urinary incontinence before pregnancy
Race/ethnicity
Child bearing started at what age?
Height (mother's height)
Overweight (weight of mother, BMI)
Inheritance (family history)
Children (number of children desired)
Estimated fetal weight

These independent factors can be given numerical values that, when added together, provide an antenatal pelvic floor trauma predictive score. This can be used by midwives, obstetricians and mothers to ensure that all are informed of realistic expected outcomes before the onset of labour, and also to help with counselling regarding PFD prevention.

In this scoring system, multiple regression models to predict PFD were developed from collaboration between the ProLong study group, SwePOP and Cleveland clinic groups. The data from of the ProLong[7] and SwePOP[8-9] studies were used to create a large database. Transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD) and complicated statistical analysis has been used to create predictive models as an online calculator to assess individualised risk of PFD for pregnant women. To follow this great work, the collaboration is planning qualitative studies as well as pilot randomised controlled trials to further evaluate the validity of such a scoring and prediction tool.

This year, the hallmark of the UGSA ASM was the focus on basic science in urogynaecology, specifically the biomechanics of urogynaecological mesh devices and their behaviour in vivo. A/Prof Moalli presented on this matter in detail, through several presentations enlightening the attendees of the cutting-edge science unveiled by the work of her team. The features of a mesh implanted in the vagina play an important role in the behaviour of the mesh. Over the past decade, there has been a move in production of transvaginal mesh devices with lower stiffness, high pore size and high porosity. Lower stiffness is critical for long-term biocompatibility of mesh devices. This is related to a phenomenon called 'stress shielding'. When two materials are connected in this process, the stiffer material bears the majority of the load and the less stiff material undergoes maladaptive remodelling response, characterised by degeneration and atrophy. This process is directly related to mesh erosion in the vagina. Therefore, lightweight, high pore size and porosity lead to less mesh material in contact with the vaginal epithelium. Furthermore, these features provide more favourable host immune response,

that is, more anti-inflammatory and less pro-inflammatory response. Another important feature of the mesh devices is the pore geometry dynamics in relation to the load on to the mesh. Pore collapse and loss of porosity leads to increased mesh load in specific areas, which then leads to increased foreign body response, encapsulation and retraction. These are directly related to pain associated with transvaginal mesh device implantation.[10-12]

We learnt from Prof Kate Moore's presentation the role of bacteriuria in detrusor overactivity (DO), with exciting pilot study results suggesting the importance of low-count bacteriuria in refractory DO. Women with refractory DO have bacteriuria rates of 39 per cent on midstream urine and 27 per cent on catheter specimen urine without acute dysuria at time of acute exacerbation of urge and that newly diagnosed DO have odds ratio (OR) of 5.9 for low count bacteriuria compared to those with a stable bladder.

Another noteworthy aspect of the meeting was the discussion led by Dr Behnia-Willison on the application of CO_2 laser therapy for treatment of vulvovaginal atrophy, specifically with the use of MonaLisa Touch™. So far, we have seen results of short-term studies investigating this modality of treatment. The session ended with the conclusion that there is not enough evidence in favour of this treatment and we need more long-term, high-powered studies to be able to critically appraise and recommend CO_2 laser therapy for the treatment of vulvovaginal atrophy.

The closing session was a focus on urogynaecology in the elderly and Prof DeLancy presented 'The Michigan four star apical suspension procedure'. In this procedure, he demonstrated a surgical technique for vault suspension, which starts at vaginal apex, excises excess vaginal length, includes both the anterior and posterior vaginal walls, attaches open vaginal cuff to ligaments and avoids descent of contralateral wall. In doing so, it creates a durable apical suspension, optimises each operative step, returns normal vaginal length, re-establishes alignment so pressures are balanced and encourages posterior repair to compensate for enlarged levator hiatus. This presentation is available on the UGSA website in the members-only section.

Dr Lin Li Ow won the UGSA travel scholarship award, while Dr Nevine te West won the best oral abstract presentation for 'Quantitative mass spectrophotometry oestriol serum levels in new and chronic users of vaginal oestriol cream'.

It is virtually impossible to highlight every presentation from such a great scientific conference; we apologise for any omissions in this short review. This meeting was the result of tremendous work and contribution from the local organising committee together with UGSA scientific committee members. We would also like to acknowledge the significant role of our sponsors who are part of our society and make these meetings possible. We hope to see you at next year's UGSA ASM in Victoria, Australia.

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Honouring Doris Gordon: the foundation of a legacy

Prof Ronald W Jones CNZM
MB ChB, MD, FRCS(Ed), FRCOG, FRANZCOG, FAOFOG(Hon)

Practitioners of obstetrics in New Zealand are standing on the foundations Doris Gordon established three-quarters of a century ago. With the re-establishment of the Doris Gordon Memorial Trust, her contribution will now be more broadly recognised.

It could be argued that Doris Gordon has made a greater contribution to the health and welfare of New Zealand women and children than any other individual. Sadly, her name and her monumental contributions have almost been forgotten. She was the catalyst in transforming largely primitive Victorian childbirth to mid-to-late twentieth century practice; she established the New Zealand Obstetrical Society in 1927, and as its long-serving honorary secretary she used the Society as the vehicle to create her visionary changes to maternal welfare. It is difficult for us today to comprehend how the vision, energy and commitment of a general practitioner from the backblocks of our country led to such enormous benefits for doctors, patients and families.

A journalist described Dr Doris (as she was always called) as: 'A severely handsome woman with a somewhat formidable manner which concealed – or sometimes cracked to reveal – a tender compassion which made her intensely and vulnerably feminine.' Going on to say that Doris used her determination and intelligence 'like a flail, a barb, a pitchfork, even a pistol, to force people to attend, and to agree, and to work, and to give, and to get things done.' During a brief time as Director of Maternal and Infant Welfare, she was described as unconventional and controversial, 'sweeping red tape out of pigeonholes, humbug out of negotiation, cotton wool out of unwilling ears – like a young hurricane on rampage.'

Doris was born in Australia in 1890, of a pioneering and missionary background. Following the financial crash in 1893, her family moved to New Zealand where her father, a part-time lay preacher, continued his banking career, becoming a manager in Tapanui, Southland. Doris initially refused to go to high school, becoming instead the paid family housekeeper. However, at 17 she decided to become a medical missionary. Doris's missionary zeal is illustrated in her writings on the fly leaf of her Bible where, from a very young age, she professed her Christian principles and goals in life. With the support of her parents, she made up for her previously patchy schooling and, in 15 months, gained her matriculation at Tapanui District High School.

At the University of Otago she wrestled with her creationist upbringing and the new Darwinian view of evolution. Despite her claim to be 'probably the most poorly qualified entrant ever

The rebirth of the Doris Gordon Memorial Trust

Following an inquiry by the Inland Revenue Department in 2011, my accountant asked if I knew anything about the Doris Gordon Memorial Trust. I had heard of the Trust, but knew nothing more; however, my recent retirement provided me with an opportunity to investigate what had happened to it. There were no living Trustees, and at that time no known Trust Deed, and although a bank account was known to exist, in the absence of a Trustee it could not be accessed. After making extensive national inquiries, I met with an enthusiastic young solicitor, Mary Joy Simpson, who finally located the Deed in the stored documents of a long-forgotten legal firm. In the absence of Trustees and with the demise of the Obstetrical Society, I sought the assistance of Mrs Marie Taylor, an active member of the National Council of Women and wife of obstetrician, the late John Taylor, and asked if she would agree to be nominated as a Trustee by the National Council of Women. The Trust bank account was finally accessed and revealed a balance of $130 000, which provided an incentive to re-establish the Trust. The Obstetrical Society had been inactive for some years so I approached the Chair of the RANZCOG New Zealand Committee, Dr John Tait, who, following consultation with the College Council, kindly agree to assist in re-establishing the obstetrics and gynaecology arm of the Trust in partnership with the National Council of Women. This required a new Trust Deed.

Following Doris Gordon's death, the New Zealand Obstetrical Society continued to play an active part in general practitioner education through regional Society groups, particularly in the Waikato region. The National Executive role was rotated around the regions; periodic meetings were held, sometimes with overseas speakers; and the Society also played an active role as a Maternity Benefits negotiator. For many years the Society contributed a regular section to the *New Zealand Medical Journal*. The New Zealand Obstetrical Society was struck off the New Zealand Register of Incorporated Societies in 2000, presumably a result of its lengthy period of inactivity. Falling numbers of GP obstetricians led to the demise of the Society in 2004, following its last meeting. I approached Dr Phillip Ashcroft, the last President of the Society, and he generously agreed to transfer the residual funds, $177 000, to the new Doris Gordon Memorial Trust.

to cross the threshold' of the Medical School in 1911, she was described as a 'brilliant medical student' and topped the class in medicine and surgery in her final year. She graduated in 1916 and, during house surgeon years in Dunedin, married a fellow medical graduate, Dr William Gordon, less than two weeks before he left on overseas war service in 1917. She also became a university lecturer in microbiology under the tutelage of Prof Sydney Champtaloup. Champtaloup was described as the driving force in the new medical laboratory and he encouraged Doris to do a Diploma in Public Health. Her brief placement in the head office of the Health Department led to her realisation that bureaucrats were frightened of newspaper publicity, an awareness she later used to good effect in her campaign for maternity reform. This experience also provided Doris with a broader appreciation of community health. It was during this time she was diagnosed with a spot on the lung that resulted in her rejection for missionary work in India. Instead, she became an obstetric missionary in New Zealand.

Following the war Doris and her husband bought a country general practice in Stratford, Taranaki. She observed: 'My Quaker-Puritan genes found an informal life in provincial Taranaki, great fun, I was well content to be the "lady-doc" to the farmers as well as a mother or sister to their women folk' – what an understatement this proved to be.

Her next eight years were consumed with domestic responsibilities and the role of a busy general practitioner/obstetrician. However, a series of obstetric disasters caused her to consider the shortcomings in her own training in obstetrics. Together with her husband, she sailed to the UK where they both gained fellowship of the Royal College of Surgeons of Edinburgh (FRCSEd). Doris, who was second in the examination with another New Zealander, Dr Leslie Averill of Christchurch, was the first Australasian woman to gain this qualification. After the examination she made the acquaintance of a number of leading British obstetricians and gynaecologists, including Victor Bonney, described as the gynaecologist of the century. She already understood the importance of networking. Following the establishment of the British (later Royal) College of Obstetricians and Gynaecologists, she became a Founding Member.

Doris was an enthusiastic advocate for safe, widely applicable methods of pain relief in labour. While male bureaucrats in the Health Department were advocating nature's ways – no doctors, no anaesthetics – she was promoting 'twilight sleep' (morphine and scopolamine). Her research on the topic led to an MD thesis, which was accepted with commendation, but she never completed the written section of the examination.

Not content with her FRCSEd, Doris was already planning the next stage of her mission: to improve the teaching of obstetrics, initially at her alma mater, the Otago Medical School. In 1926 she proposed a remit to the Napier Division of the British Medical Association, recommending the formation of a New Zealand Obstetrical Society; this was founded in Dunedin the following year. The Society was to be the vehicle for her life's mission. The stated aim of the Society was 'to correlate the efforts of individual workers and to promote the scientific study of obstetrical matters in New Zealand … and to give the art of obstetrical practice the status it so rightly deserved, but at that time lacked'. Doris said, 'We are the watchdogs to see that bureaucracy keeps obstetrics and gynaecology on a sane level and progressive keel in New Zealand.' Doris recognised that if this new Society was to achieve her long-term goals, she needed to have firm control over its destiny and, as she would later write, 'the assemblage took for granted that my husband would be the honorary treasurer and I would be the pen-driving honorary secretary.' As a consequence, she largely controlled the Society until her death.

The early Minutes of the Obstetrical Society provide a fascinating insight into the important issues of the day: the inadequate teaching of obstetrics in Dunedin; a remit to Otago University regarding the establishment of a Chair of Obstetrics; the possibility of a postgraduate school of obstetrics in New Zealand; the establishment of a resident obstetric training post for New Zealanders in Melbourne and a supporting scholarship fund; the possible involvement of the National Council of Women in fundraising; the possibility of a Maori obstetric hospital; and research into stillbirths, neonatal deaths and puerperal sepsis. The great Victor Bonney, whom Doris had recently visited in London, accepted her invitation to be present and speak following the foundation meeting of the Society. He travelled New Zealand extensively, both lecturing and fishing; described New Zealand as 'the finest country God ever made; the best rank and file doctors I have met'; and promoted an Obstetric Professorship in Dunedin. The new honorary secretary declined an honorarium.

The University of Otago accepted the Obstetrical Society's offer of a £25 000 endowment for the establishment of a Chair in Obstetrics and Gynaecology together with an undertaking that the Otago Hospital Board would build a large, new maternity hospital suitable for training medical students. Doris relished the challenge of raising the necessary funds and organised provincial committees. She enlisted the assistance of the National Council of Women and women in power. For instance, Lady Bledisloe, the wife of the Governor General, organised a supportive letter from Queen Mary, the Queen Mother. Men's groups, in particular Rotary, were supportive; every member of the ASB Board was personally interviewed, resulting in a gift of £2000. She was proud of the 'press agitation' she achieved with the editors of all major newspapers, together with the broadcasting service. While her husband ran his own practice, as well as hers, Doris criss-crossed the length and breadth of New Zealand with 'midnight journeys' addressing 200 women in Auckland, 300 in Gisborne and many thousands elsewhere; which she described as 'prospecting'. The six-month campaign raised £31 741 (current equivalent, NZ$3m) of which £25 000 was presented to the University of Otago for a chair in obstetrics and gynaecology, and the remaining £6 000 was directed for two postgraduate travelling scholarships.

Dr Bernard Dawson took up the Otago chair in 1932, impressing Doris with his 'quick brain, military precision and eloquence'. He quickly established an effective and harmonious relationship with her, aimed at improving obstetric practice in New Zealand. Later their relationship cooled when Doris promoted the development of a postgraduate department of obstetrics in Auckland, diminishing his sphere of influence.

Doris Gordon's sterling work on behalf of the women of New Zealand led to the award of an MBE in 1935, and an Honorary Fellowship of the RCOG in 1954. At this time she was the only woman outside royalty to be so honoured and the only recipient in the southern hemisphere.

Doctors in the 1930s had little knowledge or training in contraceptive instruction and were reluctant to discuss birth control with their patients. At that time New Zealand needed more, not fewer, births. The Obstetrical Society was prepared to

give instruction in birth control where reasons of the health of the mother demanded it, but only through hospital clinics. The Society was, however, concerned there was no restriction on the sale of contraceptives, including to minors, and felt it was 'contrary to the public interest' for contraceptive knowledge to reach single men and women. During this time illegal abortion was a major source of concern for the Society and women's groups, leading to the establishment of a Committee of Inquiry in 1936. During the previous year, 45 maternal deaths had been attributed to criminal abortion and the average number of children born to each of these women was eight. In 1937, together with Dr FO Bennett from Christchurch, Doris wrote a controversial polemic, 'Gentlemen of the Jury', in which they described their conservative views on contraception and the problem of illegal abortion. While this book created controversy in the community, it expressed the views held by most of the medical profession of the time. Doctors had created a dilemma for themselves: on the one hand there was an abhorrence of criminal abortion and its sequelae, while on the other a reluctance to promote birth control. The book aroused parliamentary debate, one MP observing: 'Tomorrow the Springboks play the All Blacks in Auckland. I wonder how many of the 55 000 people who will be present will realise that during the actual period of play, one child – perhaps a potential All Black – will have been wilfully destroyed in the womb of its mother.'!

If obstetric care was to progress in New Zealand it needed young trained specialists and, to this end, the vision of Doris and the Society in providing scholarships for young doctors to gain postgraduate examinations and overseas experience in obstetrics and gynaecology was farsighted. The first Scholarship was awarded in 1928, and from that time they were awarded annually. It soon became apparent that the young, newly trained specialists were not returning to New Zealand as had been hoped, but remained in the UK, where better job opportunities existed. Dr Ken Pacey from Wellington was the only scholar among the first ten awardees to return to New Zealand. Doris noted: 'The only way to get the Scholars [back] is to have a good obstetrics and gynaecology centre anywhere in the country ... our Hospital Boards were badly advised by medical interests that did not want to see gynaecology exulted as a specialty.' Doris must have sensed she would not have received the necessary support for her nascent plans in New Zealand and decided to enlist assistance from the powers that be in the UK; she attended the RCOG meeting in Edinburgh in 1939. The RCOG president, William Fletcher Shaw, was sympathetic to her plight and, together with previous scholars now permanently resident in the UK (including John Stallworthy, William Hawksworth and Robert Reynolds MacIntosh, a New Zealand anaesthetist at Oxford), they organised meetings in Manchester, Oxford and London. The outcome of these meetings was the decision to build a New Zealand postgraduate obstetric and gynaecological hospital that would attract young specialists back to the country of their birth. With British support, the Obstetrical Society resolved: 'The time has arisen for the establishment of a postgraduate centre for obstetrics and gynaecology'. It is noteworthy that Stallworthy, Doris and others made a strong case to recruit Hawksworth back to the Foundation Chair. Hawksworth's case for limited private practice (the funds to go to the departmental research fund) was the public basis for his rejection, but the real reason was personal jealousy from some senior members of the profession for his right to private practice.

In 1940, the remarkable Auckland thoracic surgeon, Douglas Robb, wrote to Doris asking if he could become a member of the Obstetrical Society. Doris described Robb as 'an academic visionary who was always in hot water with the more myopic of

Prof Ronald Jones and Alison Van Der Oest, Doris Gordon's daughter, at the RANZCOG New Zealand Annual Scientific Meeting, Wellington, 2 October 2015.

his professional brethren'. Doris and Robb formed a powerful partnership, teaming up with Stallworthy at Oxford and the College President, Fletcher Shaw, to make a case for the establishment of a postgraduate school of obstetrics and gynaecology in Auckland. Speaking at an Obstetrical Society meeting March 1941, Robb quoted the Rockefeller Foundation's lament:

> In the shadows that are deepening over Europe, the Lights of Learning are being extinguished one by one ... more and more institutes of learning are being blotted out.' New Zealand has hitherto been content to send its doctors to Europe for higher training in obstetrics and gynaecology. Now that Europe is plunged into a scientific and cultural blackout it behoves New Zealand to 'light its own light of Science' and preserve (in the South) the learning we borrowed in happier years from the old world.

Once again Doris's organisational skills came to the fore and, with the assistance of businessmen, women's groups and the public at large, £104 594 (current equivalent, NZ$7.6m) was raised to endow a postgraduate Chair in Obstetrics and Gynaecology in a new women's hospital promised by the government.

Towards the end of the war, Doris invited one of New Zealand's most eminent sons, Charles Read, an obstetrician and gynaecologist soon to be knighted following his elevation to the

Left to right: Dr Ngaire Anderson, Prof Ronald Jones, Alison Van Der Oest, Nicky Gordon (Doris Gordon's granddaughter), Matthew Heard (Doris Gordon's great-grandson), Leah Heard (Doris Gordon's great granddaughter in law) with baby Evelyn Heard (Doris' great great granddaughter), Philip Ashcroft (O&G Society), Rae Duff (President NCWNZ), further NCWNZ representative.

Presidency of the RCOG in London, to advise on matters related to the new postgraduate hospital in Auckland. Dawson, jealous of the projected new academic department, wrote to Fletcher Shaw, the immediate past-president, in London, expressing the opinion that 'someone – not a New Zealander – should be sent in order to give a more detached view'. Fletcher Shaw came instead.

Doris Gordon died in her own hospital, Marire, in Stratford, in 1956, and did not see the opening of the new National Women's Hospital in 1964. In a memorial broadcast, Robb remembered her:

> No one who knew Doris Gordon, or at least no one who was being used by her for her high purposes, would remain long in doubt about her tenacities and inflexibilities in pursuit of her ends. A mere male, the ordinary peace-loving type, might even be a little afraid of her energy and the services she required. Fear was even, on occasions, known to develop into alarm as the pressure was put on and the chariot wheels revolved faster and faster. To be of any use to Dr Doris you had to be ready to write letters, ring people up, try to put pressure on them, and generally leave your bed at any hour of the day or night. Nice work if you were pleasing her, but not so nice if you were dragging your feet or getting her to change her mind. Some mere males have even been so peevish as to characterise her communications as unparliamentary or even unscrupulous, but these persons take no account of Doris Gordon as a creative woman. Any person, male or female, who can cause to be endowed two medical chairs in the University of New Zealand in addition to leading a full professional, business and family life, as Doris did, deserves our admiration and grateful thanks.

Following her death, the New Zealand Obstetrical Society and the National Council of Women raised £4793 to establish the Doris Gordon Trust, to 'promote, sponsor, cooperate in, and otherwise further the study and/or practices of gynaecology and obstetrics'. Hawksworth delivered the first Doris Gordon Memorial Oration in New Plymouth in 1963. He recalled she was an examiner at his final oral medical assessment and he thought she was 'a bit of a dragon'. In the absence of Trust or later Obstetrical Society records it is not possible to know if there have been other memorial orations. Sadly, in recent decades, both the Doris Gordon Trust and the Obstetric Society she established have been largely forgotten. The establishment of the new Trust should hopefully restore the recognition owing to Doris Gordon.

The text of this article has been taken from the Doris Gordon Memorial Oration, delivered at the RANZCOG New Zealand Annual Scientific Meeting, Wellington, 2 October 2015.

A transcript of the Oration was frst published in the *New Zealand Medical Journal. 2016;* Vol.129, No.1437. Reproduced with permission.

FRANZCOG Training Program online portfolio

Kathryn Hertrick
Project Coordinator

The online Three-Monthly Formative Appraisal for FRANZCOG trainees was launched on 16 March for trainees in New Zealand. The Australian launch followed four weeks later. Formative Appraisals have been now completed by trainees and supervisors in New Zealand, Australia, Switzerland, the UK, Hong Kong and Papua New Guinea.

Dr Celia Devenish, Chair of the New Zealand Training Accreditation Committee, said:

> Reviewing the training assessments is always an exercise I look forward to, because seeing trainees progress through the Core and Advanced Training modules is both rewarding and reassuring. The electronic format offered by the new online portfolio adds a new dimension of ease and accessibility that is immediately addictive. The trainees readily record their thoughts and experiences and offer new insights using this modality. Our training supervisors have readily taken up the new technology, and thanks to the hard work done by the development team, there have been no real snags. I vote the change a resounding success of common sense, consensus and know how.

The next component launched was Additional Requirements. Trainees can now upload completed training requirements and submit them instantly to the College for review. Training requirements included in this component are: APSS, Workshops, Research, IHCAs, CLIMATE modules, Statement of Understanding and Activities. This new functionality also includes a dashboard for each trainee. The dashboard displays the relevant training requirements, what has been completed and what is outstanding.

The next components of the online portfolio to be implemented will be the Six-Monthly Summative Assessment and recording of leave.

Dr Celia Devenish reviews her first Three-Monthly Formative Appraisal via the online portfolio.

Pacific Associate Membership program evaluation

Dr Alec Ekeroma
FRANZCOG

Carmel Walker
Senior Coordinator
Global Health Unit

This article is an outline of the recent evaluation of the RANZCOG Pacific Associate Membership Program, released by the Board in May 2016. The full report can be accessed on the RANZCOG website at www.ranzcog.edu.au/members-services/associate-members/pacific.html.

Since 2007, RANZCOG has offered Pacific Associate Membership to medical practitioners who are recognised as specialists in obstetrics and gynaecology in a Pacific island country (PIC). This Membership includes compulsory participation in the RANZCOG Continuing Professional Development (CPD) Program for Pacific O&G Specialists, and residence in a PIC. The aim of the program is to support Pacific specialists who often work in professional isolation.

In 2015, the Pacific CPD Program for Pacific O&G Specialists Advisory Committee proposed that the Pacific Associate Membership Program be evaluated. The objectives of the evaluation were broad, looking at the delivery and impact of the program. At the time of the evaluation, there were 31 Pacific Associate Members, all participating in the CPD Program for Pacific O&G Specialists. Those that practice in the Pacific who were not Associate Members and stakeholders in the Pacific were also surveyed as part of the evaluation.

The key findings of the evaluation were largely positive. The program improved knowledge, skills and supportive networks and reduced the feelings of isolation of program participants. CPD activities such as reading, accessing educational resources, teaching, learning through teaching, audit meetings and guideline development were perceived by the participants to have improved their patient care to varying degrees.

Barriers to applying for Associate Membership have been addressed by the College over the past year, including removal of the previous annual subscription fee for Pacific Associate Members as from 30 June 2015. Matters pertaining to Associate Membership and the CPD Program are regularly communicated to Pacific colleagues and there is close collaboration with the Papua New Guinea O&G Society, the Fiji O&G Society and the Pacific Society for Reproductive Health on the provision of CPD support for specialist O&Gs in the PICs.

Analysis of the CPD program structure and participation revealed that a review of the requirements was timely and suggestions for improvements will be considered by the CPD Program for Pacific O&G Specialists Advisory Group. This Committee comprises Dr Alec Ekeroma (Chair), Profs Glen Mola and Rajat Gyaneshwar, A/Prof Amanda Noovao Hill and Drs Martin Ritossa, Miriam O'Connor and Arthur Elijah, along with College staff.

Consideration of the findings of this evaluation will strengthen the support provided by RANZCOG to Associate Members and contribute to capacity building of the O&G workforce in the PICs. The opportunity for Associate Membership and engagement in the RANZCOG CPD program is much appreciated by colleagues responsible for the provision of women's health services in the Pacific. Suggestions for improvements to the program through further engagement with Associate Members and stakeholders are included in the findings of the evaluation.

Dr Julia Singh (centre), Associate Member from Fiji, met College House staff (Katharine Ebbs and Angela Chan) during a recent fellowship visit.

RANZCOG President Michael Permezel (centre) with Pacific Associate Members at the Papua New Guinea O&G Society meeting, September 2015

Supporting maternal health projects in the Pacific

Carmel Walker
Senior Coordinator
Global Health Unit

The College acknowledges the support of Send Hope Not Flowers to the Pacific Society for Reproductive Health for maternal health projects in Pacific island countries.

On Friday 13 May, the RANZCOG Global Health Committee was pleased to host a special presentation of a donation of $30 000 by Send Hope Not Flowers (SHNF) Director, Emma Macdonald, to the Pacific Society for Reproductive Health (PSRH), represented by Dr Alec Ekeroma and Prof Peter Stone. These funds have been allocated to three maternal health projects to be undertaken in the Pacific island countries (PICs) as well as support for delivery of a PSRH Pacific Emergency Maternal and Neonatal Training train-the-trainers course in July. The projects approved by the PSRH Executive Committee are: the provision of a training room for student midwives at the University of Goroka, Papua New Guinea; a gestational diabetes research project in American Samoa; and a project to map the specialist medical workforce needs in the PICs.

Ms Macdonald said: 'Through the generosity of Australian women and their families, SHNF is happy to assist PSRH by funding these initiatives. Having just returned from a brief visit with the committed staff at the Port Moresby General Hospital, I was able to see firsthand some of the challenges and shortages faced by staff at the frontline, but I was moved by the love between the mothers and their newborns, something new mums the world over have in common. We are thrilled to be able to support PSRH in its endeavours and thank RANZCOG for inviting me here today to acknowledge the initiative.'

On accepting the funds on behalf of PSRH, Dr Alec Ekeroma said, 'We are absolutely delighted to have formed a connection with Send Hope Not Flowers. We could not fulfil our Society's aims without the kind donation of organisations such as SHNF and this donation will go a long way in enabling some of our PSRH projects to move ahead.'

The relationship between RANZCOG, SHNF and PSRH is strong, with a number of projects in progress. These support maternal healthcare at its most basic level, especially in areas of high maternal and neonatal mortality and morbidity, such as Papua New Guinea, Vanuatu and the Solomon Islands. Targeted training and upskilling opportunities, together with practical support to meet needs and overcome shortages, enable local healthcare workers to carry out their work, making all the difference. As a network, RANZCOG, PSRH and SHNF look forward to increasing and maximising opportunities to provide worthwhile, targeted and efficient projects into the future, with appropriate evaluation of those activities post-delivery.

Dr Alec Ekeroma (PSRH), Emma Macdonald (SHNF) and Peter Stone (PSRH) meet for the presentation.

Emma Macdonald, Carmel Walker and Prof Glen Mola (RANZCOG Global Health Committee) with donated supplies for Port Moresby General Hospital.

RANZCOG PATIENT INFORMATION PAMPHLETS

COMING SOON

"A more cost-effective way of providing patient information to assist with informed consent"

RANZCOG patient information pamphlets have been created to provide support to clinicians and patients in the area of informed consent. They will provide a comprehensive, relevant suite of patient information that is:

- Up to date
- Aligned with RANZCOG statements and guidelines
- Available in different languages

Topics will include:
Amniocentesis • Antenatal Care during Pregnancy • Asherman Syndrome • Breech Presentation • Caesarean Section • Chorionic Villus Sampling • Chronic Pelvic Pain • Depression During Pregnancy and Following Birth • Exercise During Pregnancy • Fetal Monitoring • GBS • Hysteroscopy • Induction of Labour • Instrument-assisted Birth • Labour and Birth • Laparoscopy • Menopause • Pain Relief in Labour and Childbirth • Planning for Pregnancy • Pudendal Neuralgia • Red Blood Cell Alloimmunisation • Travelling during Pregnancy • Vaginal Birth after Caesarean Section

For more information contact womenshealth@ranzcog.edu.au

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Excellence in Women's Health

Obituaries

Dr Michael Douglas Miller AO
(1935 – 2016)

Michael Douglas Miller was born in Brisbane, Queensland, on 30 September 1935. He attended the Church of England Grammar School and studied medicine at the University of Queensland where he graduated in 1959. In 1960 he married Jenifer Yates, with whom he had five children.

Michael undertook specialist training in obstetrics and gynaecology, obtaining his Membership of the Royal College of Obstetricians and Gynaecologists (MRCOG) in London in 1964. He joined the Royal Australian Air Force (RAAF) in 1968 and, after initial training, was posted to the RAAF Base, Amberley for medical duties, prior to being posted to the RAAF Hospital, Richmond in 1969 for surgical duties.

In 1970, Michael served a year of duty with the RAAF in South Vietnam as Senior Medical Officer, where he undertook surgical duties as well as being responsible for the aeromedical evacuation of wounded Australian Service personnel. Following this tour, he was posted as a Staff Officer to the Directorate General of Air Force Health Services, before being posted to the RAAF Hospital, Butterworth Malaysia in 1971. During his four-year tour of duty in Malaysia, he served as obstetrician and gynaecologist before being appointed Commanding Officer of the hospital.

Following further positions at the Directorate General, Michael was posted to the United States in 1977, where he was appointed as RAAF Exchange Medical Officer with Tactical Air Command. Upon his return to Australia in 1979, he was appointed Senior Medical Officer at Amberley and subsequently Principal Medical Officer, Headquarters Support Command. Michael returned to the Directorate General in 1982 and, over the next eight-years, was appointed in a range of positions, including Director General of Air Force Health Services.

Michael obtained his Fellowship of the Royal College of Obstetricians and Gynaecologists (RCOG) in 1980 and Fellowship of the Royal Australian College of Obstetricians and Gynaecologists (RACOG) in 1991. Michael was highly regarded by all members of the Health Services as an exceptional leader. On Australia Day 1989, he was awarded the Order of Australia (AO) in the Military Division for service to the RAAF as Director General of Air Force Health Services.

Towards the end of his military and medical career and following his subsequent retirement, Michael was Surgeon General with the Australian Defence Force (Ret.), and was actively involved with a number of other bodies, including St John Ambulance Australia, the National Advisory Committee on Veterans' Health RSL and the Administration Appeals Tribunal (Federal).

Michael died on 13 May 2016 and is survived by his wife of 56 years, children and 14 grandchildren.

A/Prof Anusch Yazdani
FRANZCOG
Qld

Dr James Henry Evans
(1933 – 2016)

Born in 1933, James Henry Evans was the first child of Port Melbourne Fish and Chip Shop proprietors. During his 84 years, he lived a life of medical service and achievement that spanned a period of great change in his chosen profession, much of which he contributed to.

Dux of his primary school, he attended the selective-entrance Melbourne High School before gaining admission to the University of Melbourne Medical Faculty as a 16-year-old, graduating at age 22 in 1956. He completed his intern year at the Alfred Hospital and then started his life-long work in women's health as a resident medical officer (RMO) at the Royal Women's Hospital in 1958 – an association that was to last all of his professional life, until his retirement from the hospital sector as endocrinologist-in-charge in 1996.

He was, in many ways, the co-founder of reproductive endocrinology in Australia, along with his great friend, Prof Rodney Shearman of Sydney University and former President of our College. This unusual pathway for a tyro gynaecologist followed upon completing his early O&G training at the Women's, a position as registrar in the diabetic unit of the Alfred Hospital, Melbourne.

Upon attaining the MRCOG in 1962 while in Ipswich, England, his course was further set when he obtained a registrarship in General Medicine at the Royal Infirmary in Glasgow, Scotland, which led to his satisfying the examiners of the Royal College of Physicians of Edinburgh in 1963 to gain its Membership.

His career, upon returning to Melbourne, led to appointments at the Women's Hospital and the University of Melbourne, in the Professorial Unit of Prof Sir Lance Townsend at that hospital. He was appointed firstly as an ARC Research Fellow, then as a Senior Research Fellow and then First Assistant (Reader) in the University Department. It was in these years that he forged the collaboration with Prof James Boyer Brown, the father of urinary oestrogen measurement and Dr Margery (Meg) Smith, that defined the protocols for safe and effective ovulation induction with human pituitary gonadotrophin. He served as a Member of the FSH Sub-Committee of the Human Pituitary Advisory Committee of the Department of Health from 1967 to 1987, when it was disbanded.

Notice of Deceased Fellows

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

Dr John Chalmers Thomson, New Zealand, on 16 February 2016
Dr Michael Douglas Miller, ACT, on 13 May 2016
Dr Deborah Margarette Wass, NSW, on 23 May 2016
Dr James Henry Evans, Vic, on 4 July 2016
Dr Ralph Upton, Vic, in July 2016

He retained an interest, from his early training years, in diabetes in pregnancy and was physician to the Diabetic Clinic for 30 years under the obstetric leadership of, in turn, Dr Paul Jeffrey and Dr Peter Heath within the overall leadership of Dr FIR (Skip) Martin.

In addition to heading the Endocrine Clinic at the Women's, in a long-term partnership with Prof Roger Pepperell, he played a vital shepherding and incubating role, within the male-only senior medical staff, towards Dr Jean Hailes in the inauguration of the Menopause Service and towards Dr Gytha Betheras in the establishment of the Family Planning Clinic at the Women's.

He was an ever-present, behind-the-scenes influence on the highly-prized, collegiate and social life which was an integral part of the consultant medical staff at the Women's in those days.

But it is at our College and in the editorial committee of our Journal, *ANZJOG*, that he will be remembered outside of the REI community.

From 1972 until 1986 he was, variously, a committee member, secretary or treasurer of the Victorian State Committee or the Federal Council of first, the Australian Council, RCOG, then the Australian College, following the separation but before its receiving the Royal charter; then the RACOG up until, and having played a role in the merger with our New Zealand brothers and sisters, the establishment of RANZCOG.

Between 1978 and 1981, he was a member of the Residual Committee, RCOG, which oversaw the interregnum from a British to an Australian College.

Importantly, for our new College, he, together with Lance Townsend, identified and negotiated the purchase of the extensive East Melbourne property which became RANZCOG College House.

Other State and Federal service was discharged with distinction, with membership of the Victorian Family Planning Co-ordinating Committee and the Victorian Drug Usage Advisory Committee. In the Federal arena, he was Chairman of the Women's Health Committee and Chairman of the Maternal Health and Reproduction (Standing) Committee both of the NHMRC and our College's Representative to the Pharmaceutical Benefits Advisory Committee of the Department of Health.

In 1976, James' Thesis on Ovulation Induction in the Human Female was accepted for the higher degree of Doctor of Medicine by the University of Melbourne.

He was a generous teacher of the basics and subtleties of ovulation induction to a generation of trainees and young specialists. He was invariably courteous to his colleagues and his patients. His long and distinguished career fulfilled its early promise.

James died on 4 July 2016 and is pre-deceased by his wife, Phoebe-Ann, and survived by his daughter, Bronwen, and his sons, Jonathon and David, and their families.

A/Prof John McBain
FRANZCOG
Vic

RANZCOG 2017
ANNUAL SCIENTIFIC MEETING

Skycity Convention Centre
Auckland, New Zealand
29 October to
1 November 2017

SAVE THE DATE

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

Excellence in Women's Health

College House 254 – 260 Albert Street East Melbourne VIC 3002 Australia
T +61 3 9417 1699 F +61 3 9419 0672 E ranzcog@ranzcog.edu.au

College Statements Update

July 2016

Prof Stephen Robson
FRANZCOG
Chair, Women's Health Committee

The Women's Health Committee (WHC) reviewed the following statements in July 2016, which were subsequently endorsed by Council. College statements can be viewed on the College website.

New College Statements

The following new statement was approved by RANZCOG Council and Board in July 2016:

- Exercise during pregnancy (C-Obs 62)

Revised College Statements

The following revised statements were approved by RANZCOG Council and Board in July 2016:

- Routine antenatal assessment in the absence of pregnancy complications (C-Obs 3b)
- Standing orders for prescribing narcotic drugs (C-Obs 8)
- Management of breech presentation at term (C-Obs 11)
- Altruistic and directed umbilical cord blood banking for families at risk (C-Obs 18)
- Management of vasa praevia (C-Obs 47)
- Management of hepatitis B in pregnancy (C-Obs 50)
- Management of hepatitis C in pregnancy (C-Obs 51)
- Emergency contraception (C-Gyn 11)
- Termination of pregnancy (C-Gyn 17)
- Consent and provision of information to patients in Australia (C-Gen 2a)
- Prophylactic antibiotics in obstetrics and gynaecology (C-Gen 17)

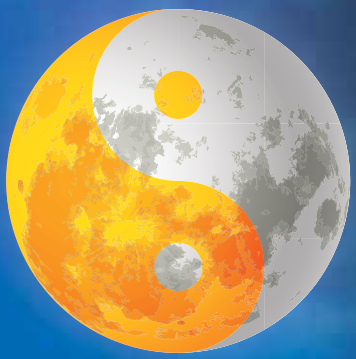
A full list of College Statements can be viewed on the Statements and Guidelines page of the RANZCOG website: www.ranzcog.edu.au/college-statements-guidelines.html.

Have you recently had a challenging, fascinating case that our readers can learn from?

Write it up.
Hit send.
See it in print.

The O&G **Magazine** Editorial Advisory Committee invite you to submit your case report for consideration to: sortenzio@ranzcog.edu.au.
Writers' guidelines are available for download on the College website.

RANZCOG 2016
ANNUAL SCIENTIFIC MEETING



PROGRAM HIGHLIGHTS & CPD POINTS

ABOUT THE MEETING

The program promises to satisfy all levels of scientific and clinical interest across the speciality of O&G; with SimWars, debates, interactive sessions and breakfast sessions, the meeting will not disappoint. The meeting theme 'East meets West' is graphically depicted by the taijitu to reflect the commonalities and differences within the speciality. Taijitu also represents the interface between the mind and body, the individual and the team, local and global health and the opportunities this meeting presents for these to come together.

PROGRAM HIGHLIGHTS

- **SimWars Session**
  Novel simulation exercises involving teamwork
- **Mind & Body Sessions**
  A perfect start to the day before attending the main program
- **Meeting Dinner at the State Reception Centre**
  Enjoy the beauty of Kings Park against the backdrop of Perth
- **O&G Debate— It is Time for an Amicable Separation Rather than a Bitter Divorce**
  Listen to leading experts' views and participate in the diiscussions via the meeting App
- **Global Health**
  Thought-provoking stories and experiences from Fellows, trainees and others who have worked in the area of global health development, humanitarian and human rights endeavours

REGISTER NOW

Visit the meeting website to register online or view the meeting program.

MAXIMISING POINTS

Fellows, Associate Members and Educational Affiliates

This meeting has been approved as a RANZCOG accredited meeting and eligible Fellows, Associate Members and Educational Affiliates of the College will earn Continuing Professional Development (CPD) points for attendance as follows:

Full Attendance (meeting only)	19 points
Attendance Monday 17 October 2016	8 points
Attendance Tuesday 18 October 2016	8 points
Attendance Wednesday 19 October 2016	4 points
Attendance Breakfast Sessions*	1 point per session

** NOTE: Yoga, Tai Chi and Mindfulness for the Practitioner Morning Sessions do not offer CPD/PD points.*

RANZCOG Diplomates

Women's Health Points — ACRRM

ACRRM has approved points for attendance as follows:

30 PRPD Points + 30 Obstetrics and Gynaecology/Women's Health MOPS Points

Women's Health Points — RACGP

The RACGP has approved Women's Health points for attendance as follows:

30 Category 2 points

Eligible GPs can apply for a two-day obstetric grant.
Both Diplomates Days are eligible for rural procedural grants.

MEETING APP

Download the "RANZCOG 2016 ASM" App to receive program notifications.

16-19 October 2016 | Crown Perth | www.ranzcog2016asm.com.au