

ol 18 No 1 Autumn 2016

Making headlines

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

PRESS



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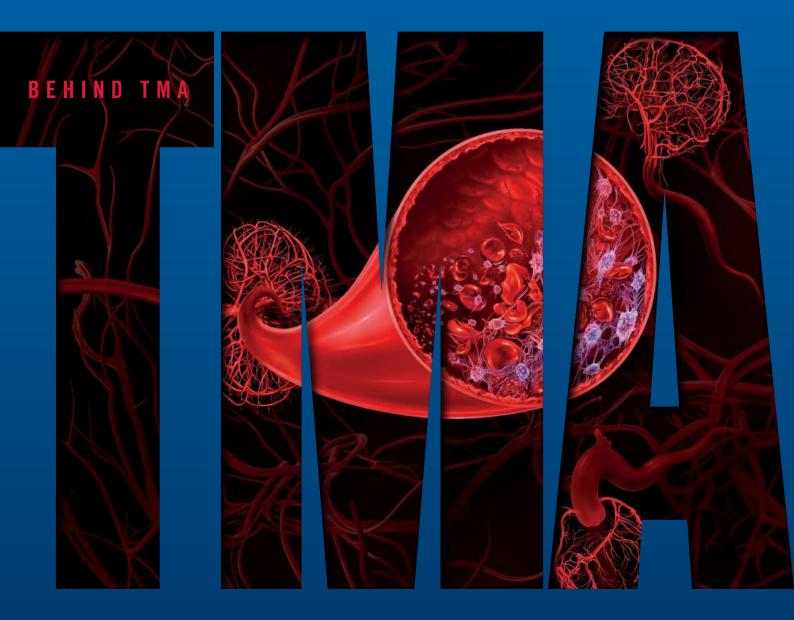
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From the President



Prof Michael Permezel President

An Obstetric Clinical Committee appointed by the Australian Department of Health has been given the task of reviewing the MBS obstetric item numbers and their associated descriptors. The objective is to support effective care while minimising unexplained variation. A priority is increased support of rural obstetrics, both for specialist and general practitioner obstetricians. Specifically, all practitioners have been told that there is not a specific savings target of the MBS review but rather a desire to place limited resources where they will best support effective care.

Items suggested for amendment

The following are items that the Obstetric Clinical Committee has suggested for amendment within the MBS schedule. It is important to appreciate that the committee has very limited scope with respect to remuneration and the focus should be on item descriptors that fit with contemporary best clinical practice. Any recommendation from the committee will go to the MBS Review Task Group and then to the Minister. Fellows and Diplomates will appreciate that any recommendations that both support effective care and reduce costs may be more likely to be accepted than those that are costed at increased expense to the health budget. The committee would welcome input from Fellows and Diplomates with respect to the suggestions below or other matters they believe should be addressed.

Pregnancy Planning and Management Item 16590 is intended to provide for the planning and management of pregnancy where the medical practitioner is

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intending to manage the labour and birth of a privately admitted patient and 16591 for those who are part of a sharedcare arrangement. It appears that there are many billings under 16590 by practitioners who never manage labour and birth. Improved descriptors may reduce this anomaly. There is currently no recognition in the MBS items of availability and telephone consultations, which are so much a part of routine care of a private obstetric patient. Many urban obstetricians invoice for these services with a substantial out-ofpocket – commonly using item 16590. MBS data reveals that our rural colleagues have substantially lower out-of-pocket billings, often leading to a significant disparity in net income from pregnancy management between urban and rural areas. Improved remuneration for rural obstetricians would be a positive outcome of the MBS review, but will be difficult to realise in the current fiscal climate. While the committee will argue for increased patient rebate for 16590 (currently \$324), this will be unlikely to happen if the overall obstetric budget is costed to increase as a result.

Recognition of mental health disorders has rightly drawn increased emphasis in our training programs. All would be aware that suicide now features prominently among the causes of maternal deaths in both Australia and New Zealand. While not being prescriptive of any specific mental health assessment, it has been suggested that ensuring a mental health assessment has been performed by a practitioner (GP or obstetrician) during pregnancy form part of the 16590 item description.

Grouped First Antenatal Visit Investigations

Many of you will have experienced the frustration of finding that key first visit investigations have been omitted by the requesting practitioner while a number of other tests have been requested for which there is no apparent explanation. It is suggested that a single item, Grouped First Antenatal Visit Investigations, be developed, which would include all the tests identified by the College and National Guidelines as indicated at this time. Of course, other investigations could still be performed as indicated, but a single item will greatly simplify the task for most practitioners.

Complex Management of Labour and Birth

Analysis has revealed considerable variation between states in the balance between 16519 and 16522. While these differences may well have a valid clinical explanation, most would acknowledge that some of the descriptors that qualify for 16522 are somewhat open to interpretation. It has been suggested that more explicit criteria will lead to more consistent use of this item number.

Antenatal Complication Attendance

One apparent anomaly of the schedule is where there is an acute presentation with a serious obstetric complication, such as severe pre-eclampsia or a major placental abruption. The attendance can be of very lengthy duration, but may only be remunerated at a level appropriate to a follow-up visit. It has been suggested that there be a time-based item, Long Consultation, in the event that such an attendance is particularly time-consuming.

Postpartum Domiciliary Attendance by a Midwife following a Privately Managed Birth – Suggested New Item

With increasing pressure to reduce length of stay, many hospitals or jurisdictions fund a domiciliary visit by a midwife in the early puerperium. Such a visit is often greatly appreciated by a new mother, but may be less available to the private patient as there is currently no MBS funding for such a visit. A new item number for such a visit has been suggested.

Parenting and training

Many of you will have read over the holiday period of the somewhat controversial title of a debate at the Tasmanian/ Victorian Regional Scientific Meeting held on 26–28 February 2016. Dr Amanda Dennis wrote an excellent reply to the controversy titled 'New Generation of Doctors Deserve Practical Advice on Professional Life, Pregnancy' which was published in an abridged format in the *Australian*. A copy can be found on the College website. The episode has highlighted the importance of increasing the College presence in social media and this will be a College priority over the next months.

Skilled Occupation List

The Skilled Occupation List (SOL) is managed by an Australian Government-appointed committee to support skilled migration. Intending immigrants from occupations on the SOL receive additional points when they apply for skilled migration or even some family sponsored migration. Given the great increases in Trainee and new Fellow numbers and future workforce predictions,



The former and current Editor-in-Chief of ANZJOG, Prof Jan Dickinson and Prof Caroline de Costa, celebrate the passing of the baton in the Frank Forster library, College House, Melbourne.

the College has made a submission recommending removal of our discipline from the SOL. This does not address the issue of workforce distribution, which remains a high priority for the College. There is also an imperative that we ensure that current Trainees receive the best possible procedural training.

'The College has been working with government representatives in both Australia and New Zealand to provide guidelines for pregnant women with respect to the outbreak of Zika virus.'

Women's health

Zika virus

The College has been working with government representatives in both Australia and New Zealand to provide guidelines for pregnant women with respect to the outbreak of Zika virus. Differences in availability of serological testing will mean that the advice for at-risk pregnancies is quite different in Australia and New Zealand. Information has been issued by the various jurisdictions (links on the College website) as well as a more specific College Communiqué advising on obstetric management where maternal infection is confirmed or probable.

PGF2 alpha

Following the discontinuation of locally produced prostaglandin F2 (PGF2) alpha, hospital pharmacies should now be able to access overseas product with either PGF2 alpha (dinoprost; Enzaprost

F) or 15-methyl-PGF2 alpha (carboprost; Prostinfenem). Usage in Australia will be via the Special Access Scheme (category A). The routes and doses of these two drugs are different and the College Statement on the management of postpartum haemorrhage has been updated to incorporate this information.

Editor-in-Chief of ANZJOG

The College is indebted to Prof Jan Dickinson's outstanding service as Editor-in-Chief of *ANZJOG* and is very pleased to welcome Prof Caroline de Costa to the position.



ASCCP 2016 UPDATE COURSES

2nd and 3rd April, Sofitel Gold Coast 17th and 18th September, Hilton Darwin

Do you need an update on the new Australian cervical cancer screening guidelines? Are you a beginner or experienced colposcopist? Then you should register for this 2 day course. The course will cover:

- Basics and principles of Colposcopy
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- HPV testing and result interpretation
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- Australian Cervical Screening Program
- Difficult management issues in cervical disease with ample time for discussion
- Quality issues in routine practice.

ASCCP 2016 TREATMENT COURSES

19th March, Royal Women's Hospital Melbourne

19th November, RPA Sydney

Do you want hands-on experience in cervical dysplasia treatment modalities

The course will cover:

- Covering technique of ablation and exicision loop and laser
- Principles of electro-surgery and laser
- Safety issues and consenting
- Analysing risks and morbidity
- Specimen handling and Pathology
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For further information and to register, visit: **WWW.asccp.com.au**

or call the ASCCP Secretariat on +61 7 3368 2422

From the CEO

As part of RANZCOG's Strategic

identified as a key objective for the coming years. Thank you to those

who completed the recent survey;

information you have provided

will help inform the Engagement

Committee and the RANZCOG

Board as to how best to improve

the College's engagement with

been analysed, a report will

be disseminated to members,

members. Once the results have

highlighting areas for improvement

and suggesting possible strategies

that the College may implement.

Plan, member engagement was



Alana Killen CEO

Social media as an engagement strategy

No matter what your personal views on social media may be – Twitter, Facebook, LinkedIn or the myriad other platforms available – there is no doubt that communication has undergone a dramatic shift in the past ten years. Information is now more readily available than ever before, and the internet has become the means by which members of the community seek knowledge, exchange ideas or share their views. Many individuals and organisations have harnessed this growing phenomenon to raise awareness of their own particular brand and the growth in popularity of some celebrities can be attributed almost entirely to their presence on social media.

'Information is now more readily available than ever before, and the internet has become the means by which members of the community seek knowledge, exchange ideas or share their views.'

Although RANZCOG may have been somewhat slow to jump on the social media bandwagon – and there are still many who are, at the very least, ambivalent or perhaps even actively opposed – there is no doubt that social media is an important engagement strategy that can promote connectedness and enhance collaboration. The Engagement Committee has been exploring various strategies for increasing member engagement and social media has been identified as an important tool to improve the effectiveness of the College's communication.

Of course, social media also has the potential to damage reputations, create tension and disseminate misinformation. Used incorrectly, the harm to organisations and individuals can be significant, so it is important, when considering social media as an engagement channel, that a strategic and thoughtful approach is taken. The influence of social media can be profound and long lasting; however, there is now an expectation that RANZCOG will form part of the broader online community and become more connected to the public and its members in this way.

Revalidation

As you may be aware, the Medical Board of Australia (MBA) is currently considering how best to ensure medical practitioners maintain and enhance their professional skills and knowledge, and remain fit to practice. An Expert Advisory Group (EAG) has been established and will be chaired by Prof Liz Farmer. This group had its first meeting in January 2016, with the objective being the provision of expert advice to the MBA on revalidation, including the development of one or more models for revalidation in Australia. The group will also provide advice to the MBA on how best to pilot the models, so that they can be evaluated for effectiveness, feasibility and acceptability.

The MBA has also commissioned social research to find out what the profession and the community expect that medical practitioners should do to demonstrate ongoing competence and fitness to practice. The research will canvas the views of medical practitioners with surveys sent to 15 000 randomly selected doctors. The social research will also seek to identify the views of members of the public in relation to expectations of medical practitioners demonstrating their ongoing knowledge and skills.

Senate Inquiry

The new Senate Inquiry into the 'Medical Complaints Process in Australia' focusing on the MBA and the Australian Health Practitioners Regulation Agency has been announced. This inquiry is co-sponsored by South Australian independent Senator Nick Xenophon and Victorian independent Senator John Madigan. The senators have raised concerns about bullying and harassment of doctors and the fairness and transparency of the medical complaints process.

RANZCOG is currently considering the issue of bullying and harassment as a priority area for action in the coming months. New resources will be developed to provide members with information and guidance in dealing with instances of bullying and harassment, and existing policies will be reviewed and enhanced where necessary.

Health Workforce Planning

The National Medical Training Advisory Network (NMTAN) was established in 2014. It provides advice to Health Ministers on issues relating to the planning, distribution and coordination of medical training and medical training plans across the medical training pipeline, from university through to vocational training. The NMTAN is currently looking at the supply and demand projections for medical specialties as some colleges are now reporting an oversupply of specialists. Although maldistribution continues to be an area of concern, there is evidence that some specialist groups may have reached saturation point, particularly in metropolitan areas.

RANZCOG continues to collect data that will help inform health workforce planning. The collection of this data is critical to ensure accuracy in modelling and projection activities, and so RANZCOG greatly appreciates the support of its members in providing this information.

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Editorial: there's no such thing as 'off the record'

'The freedom of the press works in such a way that there is not much freedom from it.'

– Grace Kelly



Julia Serafin Media and Communications Manager RANZCOG

It was a pleasure to be invited to contribute to this issue's editorial. As the College's Media Manager, I have been working at College House in Melbourne for just over ten years. It has been the most interesting and challenging role I have undertaken in the world of media relations.

Not knowing what is going to hit the press at any given moment can be both exciting and nerve-racking. It has been fascinating to see which issues attract media attention and how the general public reacts to a news story that may affect them. I am sure every doctor has patients who come into the consulting room with the words 'I heard on the news...' Phone calls at 6am from producers desperately wanting to interview the President for their early morning breakfast show and a half-hour deadline for an expert view on the 'designer vagina' illustrate just how diverse, and sometimes challenging, managing media requests on behalf of the College can be.

The College has even made its own headlines with a number of controversies, ranging from whether it supported female genital mutilation to the legalisation of

RU486 in Australia. Prof Caroline de Costa's article on RU486 is on page 44. It was imperative during these times that the College adopted a media strategy to ensure the right messages were communicated in the most effective manner – whether that was through press releases or statements posted on the website – and responded immediately to media requests for comment. Managing Director of the Media Angle, Maura Angle, provides us with some very useful basic rules to follow during a crisis (see p20).

It is important to ensure the College is both proactive and reactive in its response to media requests on women's health news that could affect our members and/ or the women they care for and their families. It is vital the College is seen as the expert voice in women's health and it is my job to ensure the College's official position is reported. I am very fortunate to have a pool of experts I can call on with a diverse range of knowledge and expertise across the specialty.

I have learned, while you can never tell which story will go viral, babies undoubtedly sell newspapers. The domination of fertility and assisted-reproductive technology (ART) stories in the media from around the world is explored by A/Prof Anusch Yazdani (see p30). We also have articles from Profs Rob Norman, Gab Kovaks and Bill Ledger that offer the insider's view of being in the middle of the story.

All the articles in this issue reflect on the theme making headlines, and I am sure you will go down memory lane when reading these fascinating articles, though perhaps not as far back as the first reported caesarean (see p60) or use of analgesia for childbirth (see p49).

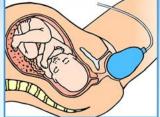
I can comfortably say that the above is all on the record, I am not sure it is going to make headlines, but I guess you will be the judge of that.



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Histological preparation of vaginal mucosa sections stained with haematoxylin and eosin (H&E)

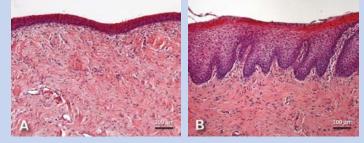
Patient data Age: 59 Age at menopause: 48

(A) Vaginal mucosa in the basal condition with a thinner epithelium typical of atrophic vaginitis. Never treated with HRT.

Note: The patient was not treated with HRT.

Courtesy of: Prof. A. Calligaro, MD Professor of Histology and Embryology at the University of Pavia, Italy

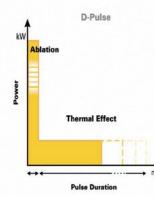
(B) Same magnification two months after one MonaLisa Touch® session showing significantly thicker epithelium of the mucosa.



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- ati, M. Serati, M. Origoni, M. Candiani, T. Ianr nucosa after fractional carbon dioxide laser nta, A. Calligaro (2014) Mic ci 2014 Nov 20
- ino Perino, Alberto Calligaro, Francesco Forlani, Corrado Tiberto, Gaspare Cucinella, Alessandro Svelato, Salvatore Saitta, Gloria Calagna (2015) Vulvo-vaginal atrophy: A new nent modality using thermo-ablative fractional CO2 laser. Maturitas 2015 Mar 25;80(3):296-301.



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Editorial: dog bites man

'If you don't read the newspaper, you're uninformed. If you read the newspaper, you're misinformed.' — Mark Twain



Prof Stephen Robson FRANZCOG

'Mark Twain' was the pen name of Samuel Clemens, and few realise that he worked as a typesetter – a dead profession if ever there was one – and newspaper writer before his professional life as a humourist began. Twain was interested and involved in scientific experimentation and technology, and held several patents. At the same time, he campaigned against animal experimentation. Through his wife Olivia Langdon he met and admired activists for women's rights and social equality.

How far have we come since Twain's day? Each of us seems to be a 'typesetter' these days, with the ability to communicate rapidly and without boundary. News comes to us in a relentless and overwhelming cascade. Yet, as Twain reminds us almost a century-and-a-half later, are we really informed or just misinformed?

I have my own story to tell and it was horrible to go through at the time. When I was the Reproductive Medicine Fellow at the University of Adelaide, in the late 1990s, my then-boss Prof Rob Norman (who has kindly written for us in the issue) asked me to drum up some publicity in an attempt to recruit more sperm donors to replenish our dwindling stocks. At the time, we only had one regular donor and things were looking grim. I managed to land a spot on ABC morning radio. Rob sensed trouble and gave me a stern warning: 'Don't say anything stupid!' He knew me well. When asked by the interviewer how many active donors we had, my reply was poorly thought through. 'We have one donor single-handedly providing our sperm supply.' Prof Norman was less than impressed, and let me know it. The unit was inundated with calls from all of the television networks and newspapers across Australia. It even ended up on the television quiz show, Good News Week, much to my chagrin. It was a bad start to a hoped-for career, but did have a positive – ultimately, the unit was contacted by 300 prospective sperm donors. I had snatched victory from the jaws of defeat. Just.

The experience made me realise just how powerful and hungry the media is. It is very easy to utter one poorly judged word or phrase and be subject to relentless consequences. In this issue of $O c^{*}G$ *Magazine*, we have revisited media stories that have caused a sensation at the time, and followed how they have played out for those involved. Stories in women's health have the potential to gather widespread media coverage, and this is something we see regularly. The College is constantly receiving calls from media organisations, asking for in-the-moment comment about new studies or reports.

We hope you enjoy reminiscing about some of the great and not-so-great moments when our specialty has hit the headlines. As always, we thank our generous authors for giving their time and experience. The team at *O&G Magazine* would very much like to hear from you. If you have something you would like to share, or comments you would like to make, please make sure you contact us. Remember the wonderful line from Oscar Wilde, 'The only thing worse than being talked about is not being talked about.'

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Thalidomide: a byword for tragedy

Dr Debra Kennedy

MBBS, FRACP, Certified Clinical Geneticist (HGSA) Director

Mothersafe, Royal Hospital for Women

Thalidomide (alpha-phthalimidoglutarimide) was initially developed as an anticonvulsant drug, but was ultimately found to be unsuitable for this indication. However, during trials it was inadvertently noted to have sedating properties. It was first introduced into clinical medicine in Germany, in 1957, and subsequently was distributed in Europe, the UK and Australia by numerous companies under several different trade names, including Contergan, Distaval and Kevadon. Thalidomide was marketed for a wide range of clinical indications, although its main use was as a sedative/tranguiliser. Later, compound preparations including thalidomide were introduced for a number of indications including asthma (Asmaval), hypertension (Tensival) and migraine (Valgraine). The drug was also prescribed to women to treat morning sickness during early pregnancy.

The first known case of thalidomide embryopathy was in a baby girl born with absent ears in Germany in 1956. Her father worked for the company (Grünenthal) making the pills and gave his wife free samples during early pregnancy. Several other cases related to women taking samples before the drug was marketed in Germany from 1957.¹

In 1961, a German paediatrician, Lenz, reported two cases of babies with congenital

limb anomalies at a German paediatrics conference and postulated that maternal exposure to thalidomide during pregnancy was the underlying cause of these defects.² One month later, in December 1961, William McBride, an Australian obstetrician, wrote a letter to the *Lancet* describing cases of unusual, severe limb defects in babies born to mothers who had taken thalidomide in early pregnancy.³

McBride noted that approximately 20 per cent of exposed infants had evidence of skeletal anomalies including polydactyly, syndactyly and limb reduction defects. Subsequent to these initial cases, further reports of affected babies came from numerous countries worldwide where the drug was available including, among others, the UK, Kenya, Sweden, Japan, Belgium, Switzerland, Canada, Peru and Brazil. There were very few cases reported from the USA, as the FDA had not allowed the drug to be released except for clinical trials, owing to concerns about reports from Europe of irreversible peripheral neuropathy and that a drug that caused nerve damage could potentially have significant effects on embryonic development. Since the drug was available over the counter in Germany, there were more affected children there than anywhere else in the world.

As the rate of thalidomide use increased in the late 1950s and early 1960s, there was a rise in the number of cases of thalidomide embryopathy, with the peaks occurring in 1961 and 1962 in Germany, with 1515 and 927 cases reported, respectively. Because the drug became available in different countries at different times, it was possible to track the epidemic of cases that became apparent seven to eight months after the drug was first introduced on to the market.¹ For example, in Canada, thalidomide was not marketed until April 1961 and, consequently, the epidemic of cases did not begin before December 1961.⁴

Owing to concerns raised about potential teratogenic effects, thalidomide was withdrawn from the market. However, just as with its introduction, withdrawal occurred over a period of time and, consequently, the end of the epidemic of thalidomide embryopathy could be documented according to when the drug was withdrawn from the market in different countries. In Germany, thalidomide was withdrawn in November 1961 and, as expected, there was a sharp decline in the number of cases reported after July/August 1962 (eight to nine months after withdrawal).¹

In recent times, thalidomide has emerged as a potential treatment for a number of conditions, including: hepatocellular carcinoma, chronic graft-versus-host disease, rash owing to systemic lupus erythematosus, Behçet's syndrome, inflammatory bowel disease, prostate cancer, metastatic breast cancer, rheumatoid arthritis and for complications of AIDS (aphthous ulcers, diarrhoea, macular degeneration, cachexia and Kaposi's sarcoma). In 1998, the FDA approved its use for the treatment of erythema nodosum leprosum (ENL).⁵

Since then, a number of cases of thalidomide embryopathy have been reported from South America,⁶ but none from the USA, where a strict program of prescribing and dispensing (STEPs Program) was implemented and has apparently been successful to date in preventing thalidomide-exposed pregnancies.⁷

Thalidomide is a true teratogen in that it can induce birth defects in the absence of maternal toxicity. One of the most important principles of teratology is that there is a critical period during which time an organism is most susceptible to the teratogenic effects of the particular agent. This critical period differs according to species (where there are different lengths of gestation).

In humans, the critical period of exposure to thalidomide is 34–50 days after the last menstrual period (LMP). In biological and basic scientific texts gestational age is often quoted as post conception, which generally occurs two weeks after the LMP. Thus the critical period for thalidomide exposure is 20–36 days after conception. Because different organ systems develop at 24 The Daily Telegraph, Thursday, July 31, 1969

THALIDOMIDE BABIES **AWARDED £33,600 IN 'TEST CASE'**

By A. J. TRAVERS

TWO "thalidomide babies" were awarded heavy damages in the High Court yesterday

Mr Justice HINCHILIFFE assessed damages for 10, 8, born without arms or legs at £52,000 and, RICHARD, 7, born without arms, at £32,000. They each receive 40 per -£220,800 for DAVID, Limited mobility

and £12,800 for Ric--a total of £53,600, RICHARD



By Morton Mintz

Staff Reporter This is the story of how the skepticism and stubb

skepticism and stubbornness of a Government physician prevented what could have been an appalling American tragedy, the birth of hundreds or indeed thousands of arm-less and legless children. The story of Dr. Frances Oldham Kelsey, a Food and Drug Administration medical officer, is not one of inspired prophesies nor of dramatic re-search breakthroughs. She saw her duty in sternly

saw her duty in sternly terms, and she ca living the while tions that she v cratic nitpicker, to - even, she carrie said That such attrib butes ed to en ascrit con



DR. FRANCES O. KELSEY

merican licensee ving the drug to sees 6 to 60 times an the comparable isage. Of 1510 offsprin is delivered with "of malformation." What she did was refuse to be hurried into approving an that the terrible effects of the application for marketing a drug abroad were widely re-considerable data arguing that why Dr. Kelsey blocked the it was ultra safe. introduction of the drug be-low months after the applica peeted by anyone. Itom was filed with the FDA, Dr. Kelsey invoked her high

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Bid to aid all Thalidomide victims

lers Company, manufacturers omide, is to against these facts: The drug had widespread use in tries. In West Germ by the babies ed primaril scription basis. It giprompt, deep, natural that was not followed hangaver. It was che-falled to kill even the be suicides who swal massive deer Richard, by Legal Aid?

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Headlines around the world: the thalidomide tragedy led to tighter control of new medicines, in general, and prescribing for pregnant women, in particular.

different times, the types of birth defects seen following exposure to thalidomide depend on the gestational timing of the exposure. It is also important to emphasise that thalidomide exposure occurring after the critical period of development would thus not be expected to cause structural anomalies.

Limb defects are probably the most recognisable and well known of thalidomide's effects, but the drug was able to induce malformations in a large number of human systems including skeletal, cardiovascular, gastro-intestinal, genito-urinary, cranio-facial and central nervous systems. Congenital malformations associated with approximate time periods within this 17-day time period include (days after LMP): anotia (34–38 days), microtia (39–43 days), thumb duplication (35–38

days), thumb aplasia (35-43 days), thumb hypoplasia (38-40 days), eye defects (35-42 days), cardiovascular defects (36-45 days), vaginal duplication (35–39 days), cranial nerve palsy (35-37 days), amelia of upper limbs (38-43 days), phocomelia of upper limbs (38 to 47-49 days), amelia of lower limbs (41–45 days), phocomelia of lower limbs (40 or 42-47 days), choanal atresia (43–46 days), duodenal atresia (40-47 days), anal atresia (41-43 days), gallbladder aplasia (42–43 days), pyloric stenosis (40–47 days), duodenal stenosis (41-48 days), rectal stenosis (49-50 days), ectopic kidney and hydronephrosis (38–43 days) and abnormal lobation of lungs (43-46 days).12,13

Estimates of the risk of development of congenital malformations in offspring

exposed to thalidomide during the critical period range from ten to 50 per cent.¹³ The reason there is such a large degree of uncertainty in this estimate is due to the lack of epidemiological studies, as well as the inability to determine the number of exposed but unaffected children. It is also worth noting that the early mortality rate among babies exposed to thalidomide was approximately 40 per cent, owing to the presence of severe internal malformations (such as, for example, cardiovascular and gastro-intestinal).

It is still unclear what factors determined whether or not an exposed embryo was affected and, if so, which systems were involved. An interesting case of a twin pregnancy was reported with the offspring showing very different manifestations of

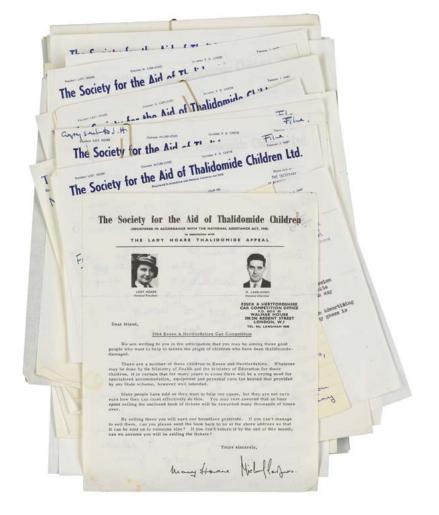
thalidomide embryopathy after the same exposure. The first twin was a female weighing 2211g at birth born with duodenal atresia, a recto-perineal fistula and hypoplastic dislocated thumbs. The second twin, a male weighing 2240g at birth, had phocomelia of both upper limbs as well as missing/hypoplastic digits on both hands and a midline hemangioma of the forehead.¹⁴

Thalidomide significantly changed the way in which risks of medication in pregnancy were perceived and how medications were assessed in terms of potential reproductive risks. This has had both positive and negative ramifications.

In 1963, as a direct consequence of the thalidomide tragedy, the Commonwealth Department of Health established the Australian Drug Evaluation Committee (ADEC) as an independent committee to advise on the safety of new drugs being introduced into Australia and to monitor and evaluate potential adverse effects of drugs already available. In 2010, ADEC was replaced by the Advisory Committee on Prescription Medicines (ACPM). The Australian categorisation of risk of drug use in pregnancy (A-X) was established by ADEC, is still in use today and largely dictates medication prescribing in pregnancy and how risks of medications in pregnancy are perceived by both healthcare professionals and consumers.

Although ADEC's aim was to prevent a similar tragedy occurring with any future medications, what has actually occurred is that healthcare professionals have become extremely cautious and risk-averse about prescribing (or dispensing) medications during pregnancy because of perceived (and often greatly exaggerated) fears of teratogenicity, not considering that the risks of untreated illness in most cases are far greater than the often theoretical risks of teratogenicity. This has resulted in large numbers of women being untreated or under-treated for significant medical conditions that could adversely affect their health and that of their unborn baby during pregnancy. In addition, some women go so far as to terminate or seriously consider terminating otherwise-wanted pregnancies because of these fears of teratogenicity.

Fortunately, there has not been another 'thalidomide' since the early 1960s and hopefully such a tragedy will not occur in the future. However, it is important that we enter a new era of rational evidencebased prescribing and medication use



As was recognised at the time, the ramifications of the thalidomide tragedy will last for a generation or more. (Wellcome Library, London, reproduced under licence CC BY 4.0.)

in pregnancy so that both women and healthcare professionals understand the pros and cons of appropriate medication use during pregnancy and (breastfeeding) and can make rational decisions, thereby optimising the health of pregnant women and their babies.

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Standing up to the Grim Reaper: the early days of AIDS

Dr Alex Wodak AM

Emeritus Consultant Alcohol and Drug Service, St Vincent's Hospital Visiting Fellow Kirby Institute, UNSW President Australian Drug Law Reform Foundation Director Australia21

In 1977, my wife and I attended a small gathering of friends in London, where we were living at the time. Ari, a visiting young American gay man performed *bharatanatyam*, a South Indian dance. A couple of years later, I heard that Ari was declining rapidly with some sort of baffling immune condition. Then I heard that Ari had died. Later, I remember reading a small article in the *Times* announcing, on 5 June 1981, the recognition of a new and mysterious immune disease, later called AIDS, now called HIV infection.

In 1981, on my way to an interview for a possible alcohol and drug position at St Vincent's Hospital, Sydney, a young woman in a dirty grey singlet and sporting impressive track marks approached me in the street to enquire whether I would 'like to have a good time'. I replied 'No, thank you', but I decided that this was the hospital I would love to work at. I got the job.

I will never forget the first case of AIDS admitted under my care at St Vincent's Hospital in the mid-1980s: a young gay New Zealander who had come to Sydney after several years living in the USA. I spent a lot of time doing oesophagoscopies and sigmoidoscopies on severely ill gay young men to diagnose a condition that was then untreatable and often rapidly terminal.

Bit by bit, the nature of this epidemic became clearer. The magnitude of the threat was uncertain, but it was clear from the outset that potentially this was a serious threat to the health, well-being and economy of Australia. If anything, the early assessments turned out to be far too optimistic. The media largely ignored the epidemic until the Grim Reaper advertisements began appearing in April 1987. Though intended to persuade the (then) Treasurer, Paul Keating, to allocate sufficient funds for AIDS in the next Budget, the advertisements shifted AIDS from small paragraphs buried on an inside page of our newspapers to headlines on the first page. The Treasurer put aside sufficient funds in

the 1987 Budget for a vigorous national response to HIV.

St Vincent's Hospital was in the epicentre of this new epidemic. Thousands of gay men in the neighbourhood had rapidly become infected in the early 1980s. It was clear that there was a frightening risk of a cascade of HIV infections starting among gay men, spreading from gay men who used drugs to their heterosexual counterparts through needle sharing and then spreading to the general community through sexual contact. Once the genie was out of the bottle, getting it back in again was going to be a nightmare. I spent sleepless nights worrying about this.

A group of healthcare workers and people who used drugs started meeting regularly to discuss what we should do. It was clear that starting a program to swap sterile needles and syringes for used injecting equipment was the most urgent priority. I had been asked to coordinate a national workshop on cocaine and allocated Dr Stan Yancovits, an infectious disease physician from New York, to be the main speaker. I rang Dr Yancovits and asked him if he would be willing to speak about HIV while in Australia and to also, perhaps, support starting needle exchange. He was more than willing. He spoke about a nurse in his hospital who had died from AIDS after being infected years earlier by a previous husband, leaving behind her second husband and a number of small children. Dr Yancovits described how she had written out her will while dying. Chilling stuff. I wrote many submissions to the NSW Health Department begging to be allowed to start a needle syringe

The Sydney Morning Herald

The commercial that scared us - and might have saved us



IT LASTED only 60 seconds and ran for just three weeks - but 25 years later, we're still talking about it. The most famous ad in Australia's history: AIDS and the Grim Reaper, which first aired on April 5, 1987.

It terrified nearly everyone. A Gothic Grim Reaper, all tattered robes and decaying flesh,



In 1987, the National Advisory Committee on AIDS ran a television advertising campaign depicting the Grim Reaper bowling in a bowling alley and knocking over men, women, and child 'pins', representing AIDS victims. It is still considered a landmark in advertising and shifted the focus of the debate.

AIDS breakthrough hope

CANBERRA. — Australia could be the first country to isolate the AIDS virus, leading to a possible cure, according to the head of the Federal Government's working party on AIDS, Professor David Penington. Australia's fourth AIDS (acquired immune deficiency syndrome) victim is at present critically ill in hospital. The victim's name and the location of the bospital are being kept secret. AIDS

and the location of the nospinal are occurs kept secret. In the past 12 months, three other Aus-tralian men have contracted a severe form of the divease. Two died in hospital in Mel-bourne and another has apparently recovered and is living in Sydney. All were homosexual or bisexual.

world In isolating the virus suspected of causing AIDS because the full force of medi-cal research in the country was prime deal with it.

deal with it. "In America, by the time they knew they had a problem with AIDS, it was already a widespread problem. But we have an oppor-tunity to identify the discase early with the use of particular tests and the co-operation of the gay community." It cases could be identified early, there was more chance of identifying the causes of the discase and possibly developing vaccines, he said.

according to Sydney gay activity Lex Watton and the media and the media had led to the hysterical labeling of AIDS as the "gay cancer," according to Sydney gay activity Lex Watton.

ensues, smarp and Dohme, manufactur-ers of the hepatitis B vaccine, to reasssure the public that although blood donors for the vaccine's production included gay men, it did not carry a risk of transmitting AIDS.

'hysteria' on Al

Gays indignant over

cases, both here and in the States of discrimination agains within the health profession, the here and in the United gay: place, and even among delivery based on the fear of AIDS." he said



Newspaper stories from Australia in 1983 and 1984, as news of the first cases of AIDS broke. Clippings collected by Paul Kidd (http://realtimeaids.com). Copyright in quoted or reproduced media stories and articles remains with the holder and materials are reproduced for non-commercial, educational purposes only.

program. Later, a friend working in the Health Department was asked to clean up some shelves and came across 13 separate submissions written by me. All had been declined or ignored.

We also knew that the methadone program had to be expanded and liberalised. I arranged for Dr Yancovits to speak to the state committee. The committee then agreed to support expansion and liberalisation. The numbers on the NSW methadone program started to rapidly increase.

We eventually realised that the NSW Health Department was never going to approve a needle syringe program before the epidemic had started. So we had to resort to civil disobedience. The first needle and syringe was handed out on 13 November 1986. It was a big decision for every member of the group. My regret is that we did not start earlier. Now, almost 20 years later,

the prevalence of HIV among Australians who inject drugs (and have no other risk factors) is still less than two per cent. Half the needle syringe programs in the world were started by civil disobedience. Some countries were not as lucky and, with no needle syringe programs and minimal or no methadone program, HIV spread among and from people who inject drugs to the general community. In Thailand, the prevalence of HIV among people who inject drugs increased from less than one per cent to more than 40 per cent in ten months in 1987. Within five years in the north-west of the country, one-in-12 pregnant women and one-in-six male military recruits had HIV infection. That could also have been Australia's story.

Much as I support research, I was delighted to learn that a study of HIV infection in children run from the Sydney Children's Hospital in the 1990s had to be cancelled

as there were not enough HIV-infected children to carry out the study.

Although I have received a lot of credit for this response, the truth is that it could never have happened without many others, healthcare workers and people who inject drugs, sharing the work and the risk. We were lucky to have the strong support of many senior health department officials, policymakers and politicians. Peter Baume, the (then) Shadow Health Minister, had to persuade the (then) Opposition Leader, John Howard, and Neal Blewett, the (then) Health Minister, had the easier task of persuading the (then) Prime Minister, Bob Hawke to allow pragmatism to triumph over shortterm political gains.

One of the lessons from this episode is if you want to make some serious health gains, the target population has to be meaningfully involved every step of the way.

How to deal with the media during a crisis

Maura Angle Managing Director The Media Angle

A long time ago in a galaxy not so far, far away, the first three key words used in response to a crisis were: deny, deny, deny! For example, for many years, the Catholic Church's response to child abuse was often to deny any wrongdoing. That approach has not done their reputation or the victims any good in the short or long term. Thankfully, this old-fashioned and ineffective ethos is becoming known as the wrong way to deal publicly with a crisis situation, but there are still plenty of examples of how not to react.

Another far-too-common mistake is avoidance: avoiding the media, avoiding any victims or avoiding the place where the crisis took place. The chairman of Montreal, Maine & Atlantic Railway Ltd, Ed Burkhardt, was heavily criticised for waiting four days to address the public and media in the small Canadian town of Lac Megantic after an accident that killed 40 people in 2013.

When a crisis occurs to you or your organisation a large part of your crisis plan is to limit the damage as much as possible. Denial and avoidance rarely help. It is far better to be as open and honest as you can, as soon as you can. It may even involve falling on your sword or light sabre, to continue the Star Wars theme.

Take the recent 'wrong text message' saga as an example. Earlier this year, the Australian Immigration Minister, Peter Dutton, had a serious case of text regret after sending a rather offensive message about a female journalist to that very journalist. He referred to her as a 'mad f---ing witch'. The message was reportedly meant to be sent to his colleague Jamie Briggs after he had stood down after inappropriate behavior towards a staffer while on an overseas trip. Mr Dutton admitted the texting error soon after the journalist went public with the mistake. He also immediately apologised to the journalist. The minister still had to deal with the damaging effects of his bad language and mistake, but his prompt and honest actions would have helped to reduce the impact, at least a little.

A prompt and simple apology can go a long way. It sends all the right messages to any

Some basic rules to follow during a crisis

- 1. Don't panic. Stay calm, get advice quickly and be ready to react in a measured way. If you look like you are panicking, the public are likely to do the same.
- 2. Go public with a response as soon as you can. Avoiding the public and media will often make things far worse for you. Engage with the public as soon as you can. You/ your organisation will suffer in the short-term, but informing the public early will help reduce the risk of long-term damage.
- 3. Acknowledge what you did wrong or what went wrong. Being open about what went wrong is also vital during a crisis, especially when human lives are at risk. Even when lives are not at risk, denying responsibility for a crisis you are clearly to blame for is foolish. If you don't know who is to blame at least acknowledge that something has gone wrong and you are trying to fix the problem and investigate.
- 4. Empathy or an apology must be part of your message. You must always put the victims or those affected first. Your message must be about them and how sorry you are for hurting/inconveniencing them. Your response should address what you are doing to help them and fix the problem that has caused them distress. Who can forget the barrage of criticism directed at former BP boss Tony Hayward after the deadly Gulf of Mexico oil disaster? He not only chose to go sailing with his son in the immediate aftermath of the spill that killed 11 workers, but he also said publicly, 'I'd like my life back'.
- 5. Outline what you are doing to fix the problem. If your computer system is down and thousands of customers can't do their online banking or they can't get on the flight they booked months ago, there is little doubt that you are trying to fix the problem. Even if you are yet to find a solution, your customers want to know that you are trying to solve the issue. So tell them.
- 6. Keep the public informed. You need to keep the public informed as the crisis unfolds or as you work on a solution. This is especially important when a crisis is unfolding, for example, natural disasters, fires and disease outbreaks.

victims or members of the public affected. It tells them you empathise with them and want to deal with the situation in a timely and honest manner. There are times when you cannot say sorry, owing to the fact it may not be clear who is to blame, but even then you can empathise with those adversely affected.

Imagine if there was a fire at your hospital or surgery and a number of patients died in the blaze. You can still show empathy without accepting blame in the immediate aftermath. You could, for example, say 'we are sorry for all those families who have lost loved ones due to this awful fire. The fire authorities and police are investigating what went wrong, but until we know how it started we just want everyone to know we are doing all we can to help those involved.'

It's a crisis you will hopefully never have to cope with, but you and your employers may at some stage have to deal with a situation that may potentially damage your reputation irreparably if you don't handle it the right way. In the box is a list of some basic rules to help you and your communications team deal with any potential crisis, but in the meantime I urge you to share my vision where the first three words used in response to a crisis are not 'deny, deny, deny' but 'I am sorry'.

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Hormone alert for cancer: how not to release data from your RCT



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On 9 July 2002, women around the world awoke to bold newspaper headlines and strident radio and television journalists trumpeting the harms of hormone replacement therapy (HRT), following the release of the first publication of data from the Women's Health Initiative (WHI) randomised controlled trial (RCT).

The Sydney Morning Herald, under a banner headline 'Hormone alert for cancer', declared 'up to 600 000 Australian women had been advised to stop taking HRT as new research revealed it increases their risk of cancer'. The article went on to say: 'The Cancer Council of NSW has called for women's access to HRT to be restricted'. WHI was commissioned by the US National Institutes of Health (NIH) in 1991 and sought to address the most common causes of death, disability and impaired quality of life in postmenopausal women. It was the largest US prevention study of its kind, costing upward of US \$725 million and running for 15 years.

There were three components:

- a randomised controlled clinical trial of promising, but unproven, approaches to prevention;
- 2. an observational study to identify predictors of disease; and
- a study of community approaches to developing healthful behaviours.

A total of 161 808 women aged 50–79 were recruited, of whom 68 132 were involved in clinical trials. The 'unproven' approaches to prevention included: dietary modifications, calcium and vitamin D supplementation, and HRT.

The HRT RCT was intended to test the hypothesis that women receiving HRT would have lower rates of coronary heart disease and osteoporosis-related fractures than the placebo group. A substantial body of observational data had suggested this would be the case.

It is important to note that the original protocol explained that WHI would recruit women older than those included in typical RCTs with about two-thirds of the cohort over 60 years of age and that follow up would be longer than any previous trial. The primary aim was to see what happened to women who commenced HRT at an older age. This was not a trial of symptomatic, recently postmenopausal women.

The investigators correctly noted that, while considerable evidence suggested bone and cardiovascular benefit from HRT for women in early menopause, there was little pertinent data about the effects of starting HRT later, especially after age 60. The significance of age at initiation of therapy seems then to have been lost on the investigators for almost a decade.

The first WHI results were released at a press conference on 9 July 2002, before the publication of the paper in the *Journal* of the American Medical Association (*JAMA*) one week later. The data were rushed to the news media in what one commentator, Dr Scott Gottlieb, a former senior official with NIH, described as a 'carefully orchestrated PR blitz'. Chaos ensued; women were told to 'stop their HRT and go to their doctor'.

Doctors, except it seems some linked to cancer councils, had no access to the unpublished data for more than a week and few knew anything of the paper. Even the principal investigators of WHI did not have an opportunity to review the data prior to release. The data were not completely adjudicated and, in a breach of protocol, were not released in age cohorts.

HRT, it was said, caused cancer, thrombosis and dementia, worsened heart disease and did little to alter quality of life. Results were conveyed, sensationally, as relative, not absolute, risks and not all were statistically significant. Relative risk (RR) describes the degree of change in a risk over the baseline rate whereas absolute risk provides the actual number of cases increased or decreased in a given population. While initial RRs made for sensational reading the absolute risks were small, making them 'rare' in World Health Organization terminology. Poor understanding of this important difference led the Sydney Morning Herald, in an article published on 10 July 2002, to confidently report that women taking HRT would sustain 41 per cent more strokes, 29 per cent more heart attacks and 26 per cent more breast cancer.

The NIH Chief Investigator, Jacques Rossouw, told the press conference that the adverse effects applied to all women irrespective of age, ethnicity or disease status. In a remarkable example of hubris he was also quoted as saying 'NIH was

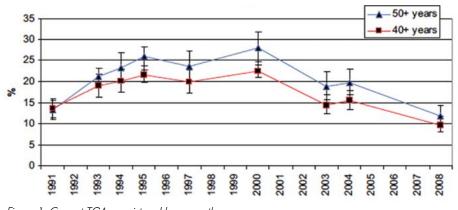


Figure 1. Current TGA – registered hormone therapy use.

going for high impact with the goal to shake up the medical establishment and change their thinking about hormones'. He must have been delighted with the results of his efforts: many women ceased HRT at once. Doctors were frightened to prescribe such 'dangerous' medications and many harboured a sense of resentment against 'experts' who had promoted the benefits of the now 'disgraced' therapy.

In July 2002, approximately 25 per cent of recently postmenopausal women were current or past users of HRT. Most recent data suggest only six to seven per cent of US women and five per cent of Australian women in their 50s are current users (see Figure 1). Many women who abandoned HRT turned to complementary medicines or bio-identical hormones, which they

perceived to be safer, but for which there were limited evidence of efficacy and no evidence of safety. In some, but not all, countries breast cancer incidence declined, plateaued and then began to rise again. By 2005, data had emerged to suggest that age-adjusted osteoporotic fractures had increased compared with 2001–2 and, in 2013, a paper using theoretical assumptions of prior and current oestrogen replacement therapy use estimated that up to 91 000 postmenopausal US women died prematurely because of avoidance of oestrogen therapy. And yet, in the ten years since WHI researchers first unveiled their results, a series of follow-up studies using the same government data found that many of the initial conclusions were premature, indefinite or just plain wrong.

Critically, although the government initially said the findings applied to all women, regardless of age or health status, subsequent studies showed that the age of a woman and the timing of hormone use dramatically change the risk and benefits – just as the original protocol had postulated. In fact, the findings of these studies seem to directly contradict some of the government's initial conclusions.

For example, women in their 50s who took a combination of oestrogen and progestin or oestrogen alone had a lower risk of dying than women who didn't take hormones. Also, women in their 50s who regularly used oestrogen alone had a lower risk for severe coronary artery calcium, a risk factor for heart attack, a reduced risk of coronary heart disease and breast cancer and a reduced risk of allcause mortality.

In 2013, the WHI investigators published results of long-term follow up from both arms of the trial. For women aged 50–59 or within ten years of their last menstrual period, there was no statistically significant increase in any adverse outcome for users of HRT. For users of oestrogen alone, risk of coronary heart disease, the commonest cause of death in postmenopausal women, was significantly reduced.

The WHI investigators and the NIH refused to share the raw data from the trial even

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The anatomy of a health scare: headlines are not the place for nuanced reporting of complex results. (Clippings collected by the author.)

with outside academics or the companies that manufactured the study drugs. They were thus able to protect their monopoly over the data and their prerogative to publish follow-up data as and when they saw fit. With the benefit of hindsight it seems likely, had the data been more widely shared, important analyses of the data that debunked original conclusions would have come to light much sooner to the benefit of postmenopausal women and their doctors.

'The ultimate goal should be to help ensure that science and patient care are...free from the inappropriate influences of industry, government and politics.'

Governments now play increasing roles in the healthcare of patients, and the objectives of governments may at times be at odds with the interests of the individual patient and hence the professional obligations of their physician. Appropriately, greater transparency has been sought in the interaction of the pharmaceutical industry with physicians and similar transparency should also be applied to the interaction of governments with physicians. Author conflict-of-interest statements in journal articles should include funding received from industry or government agencies. Journals now maintain arms-length relations with the pharmaceutical industry and also with government sponsors. Journal editors should select reviewers for all manuscripts using similarly strict impartiality. Reviewers should review manuscripts with the same thoroughness, regardless of the funding source. The ultimate goal should be to help ensure that science and patient care are, to the extent possible, free from the inappropriate influences of industry, government and politics.

The role of the media release is also critical. A 1998 paper, published in JAMA, examining the source of newspaper articles on scientific topics, found 84 per cent referred to articles mentioned in press releases. In June 2002, a paper in JAMA entitled 'Press Releases' reported that in a survey of nine medical journals, involving 127 press releases, study limitations were rarely mentioned, industry (or government) funding was not mentioned and data were often presented using formats that may exaggerate the perceived importance of findings. The importance of a properly conducted press conference could not be better stated and yet, one month later, that same journal held the WHI press conference, did not discuss study limitations or sources of funding and exaggerated the significance of findings.

Can it happen here? Yes, of course. Journals prosper not only from good scientific papers, but also from circulation, advertising and publicity. If you have a 'newsworthy' paper accepted, even by our own esteemed *ANZJOG* (of which I am an associate editor) you will be asked to consider a press release and offered the services of the publisher's marketing department to make sure the impact is maximised. Of course, exaggerating your results will help!

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Key points

- 1. WHI was a well-designed, large, long-running RCT to test the hypothesis that HRT given to older postmenopausal women would reduce the burden of diseases of ageing.
- 2. Despite this, when the data were released, they were said to be applicable to postmenopausal women of all ages, ethnicities and health.
- 3. The data were released before complete adjudication, without prior approval of all principal authors and before publication.
- 4. Data were released in a sensational, confrontational manner to obtain maximum publicity and referred only to relative rather than absolute risks.
- 5. Rigour was not evident in statistical analysis, nominal or adjusted confidence limits were not always correctly applied and results were not always supported by statistical significance.
- 6. Failure of the government to release the raw data from the trial prevented independent analysis and may have delayed further analyses that overturned many of the original findings.
- 7. Medical journals have a critical role to play in the dissemination of medical research. Strict authorship guidelines must be adhered to. Reviewers must be diligent and independent, statistical analysis should be verified and significance of findings confirmed and data presented in a clear concise manner.
- 8. Press releases should not be sent out before the paper has been published and is available to the medical profession; data should be released in a factually honest manner.
- 9. Collaboration of bodies such as the Australian Science Media Centre, to assist journalists in the correct interpretation of scientific data, should be considered.





The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

EAST MEETS WEST





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WELCOME, REGISTRATION & CALL FOR ABSTRACTS

WANJU - WELCOME

The meeting theme 'East meets West' is graphically depicted by the taijitu - the Chinese symbol for the concept of yin yang - to reflect the commonalities and differences within our 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.

Our Organising Committee has produced a program of wide appeal, promising to satisfy all levels of scientific and clinical interest across our speciality.

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A/Prof Paul McGurgan, Chair, Organising Committee Prof Yee Leung, Chair, Scientific Program

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Trainee / Diplomate / General Practitioner	A\$ 930	A\$1,165	
Pacific O&G Specialist / Midwife / Retired Fellow	A\$ 620	A\$ 775	
Low Resource Country	A\$ 420	A\$ 420	
Medical Student (full time)	A\$ 225	A\$ 225	
DAY REGISTRATION	EARLY BIRD	STANDARD	
Fellow / Specialist	A\$ 500	A\$ 660	
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Trainee / Diplomate / General Practitioner	A\$ 375	A\$ 495	
Trainee / Diplomate / General Practitioner Pacific O&G Specialist / Midwife / Retired Fellow	A\$ 375 A\$ 250		
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- Diplomates Day Two: Gynaecology
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- Obstetric Ultrasound Workshop
- Paediatric Gynaecology Workshop
- RANZCOG Training Supervisors Workshop
- Urogynaecology Dilemmas and Disasters
- (Satellite meeting run by the UroGynaecological Society of Australasia - UGSA)

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Abstracts are invited for Free Communication Oral and Poster Presentation on any topic relevant to women's health.

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Tales from the test tube revolution

Prof Gab Kovacs AM MBBS, MD, FRCOG, FRACOG, CREI

The in-vitro fertilisation (IVF) research program began as a joint effort between Melbourne and Monash Universities at the Queen Victoria Hospital (QVH) and the Royal Women's Hospital (RWH) in 1970, under the guidance of a committee chaired by Prof Carl Wood.

The initial team included Carl Wood, John Leeton and Alex Lopata from Monash University, and Ian Johnston and James Brown from Melbourne University - RWH. It was called 'the egg project'.

The team produced the world's first human IVF pregnancy in 1973. Nicknamed the 'test-tube baby', the team took an egg from a 36-year-old woman and fertilised it in a test tube; three days later, the embryo was implanted in her womb. The pregnancy lasted nine days after the implantation – classified as a biochemical pregnancy, meaning that the pregnancy test was definitely positive – but it did not progress further. This revolutionary research was published in the Lancet. A few weeks later the front page from the Herald on Thursday 20 August 1973 (on display in the College museum), outlined the plans to progress with further attempts to achieve successful pregnancies, with photos of Carl Wood and John Leeton.

Despite continuing attempts for several years, no further pregnancies were obtained. However, these early results sparked excitement in fertility treatment and spurred on other research teams, particularly in the UK, where Robert Edwards had been working on the

collection and maturation of human eggs in vitro since the 1960s. At the time, the only treatment for fallopian tube blockage was surgery with very limited success, and most women with blocked tubes were unable to become pregnant.

In 1977, a substantial grant was received by the Melbourne team from the Ford Foundation; who were keen to support the project as they thought the basic scientific information obtained may help in the development of new contraceptives. However, they did not want to be acknowledged if an IVF birth occurred. This grant allowed Alan Trounson, a scientist with experience in animal IVF in both Australia (in Jerilderee where he worked with Prof Moore on sheep IVF) and the UK, to be recruited to join the team.

In 1976 Steptoe and Edwards achieved a pregnancy in the UK, albeit an ectopic tubal pregnancy where the embryo implanted in the fallopian tube.¹ Finally, in 1978, the first human IVF birth (Louise Brown) was reported by Steptoe and Edwards in the UK after 102 attempts at embryo transfer² (followed by a second birth, Alastair McDonald, which was achieved in January 1979).

Hearing about the British success, the Melbourne team approached IVF with new vigour. Even before there was any real success, Trounson commenced publishing articles on the new knowledge gained, such as the application of IVF to unexplained subfertility.³

The combined team achieved the third IVF birth in the world and the first ongoing pregnancy in Australia. The front page of the Sun from 7 February 1980 shows lan Johnston holding a media conference

announcing the pregnancy at five months, and this can also be seen in the College Museum in Melbourne. The paper also shows photos of the other long-term members of the team, Carl Wood, Alex Lopata and John Leeton.⁴ Candice Reed was subsequently born in June 1980, at the RWH

The teams then split, the team at the RWH including Johnston, Lopata, Spiers and McBain, and the Monash team working at the QVH with Carl Wood, John Leeton, Alan Trounson and myself. James (Mac) Talbot, who was involved with the 1973 pregnancy and who had an appointment in the Infertility Clinic at QVH, rejoined the team later.

The Monash team achieved no pregnancies at the QVH and moved to St Andrews Hospital in 1980. In natural cycles with only one follicle and laparoscopic oocyte collections, the procedure often took over an hour. As the cycles were done with spontaneous ovulation, the women had to be monitored 24 hours around the clock (with three hourly urine specimens) looking for a rise in luteinising hormone (LH). The time for oocyte collection was then 36 hours later, and often at 2am, 4am or 6am. Being an IVF clinician was like being an obstetrician – working all hours. The theatre staff were not happy to be called in for an operation that so far had no proven results. The follicle had to be visualised and often these women had pelvic adhesions and/or endometriosis, it was then aspirated, irrigated (flushed) and curetted with the needle, while trying not lose the oocyte, quite a challenge. If we managed to collect the oocyte, it was almost a celebration. Then this single oocyte had to fertilise and develop, and ultimately implant. Our instruments were simple, the embryo transfer catheter made of stainless steel and traumatic. At the instigation of Alan Trounson, we started using stimulated cycles using the hormone

The program for in vitro fertilization at Norfolk*

Howard W. Jenes, Jr., M.D.1: Georgeanna Scegar Jones, M.D.1 The Norfolk program greatly benefited fre visits to and from the two active Australian p grams in Melbourne, with the result that it w possible for us to utilize their very great expe ence.

Based on available information, it seemed sential to provide for the initiation of a progra

Figure 1. Clipping from the Jones report, thanking the Melbourne teams.

clomiphene citrate. This resulted in multiple follicles developing rather than only the one in a spontaneous cycle, giving a better choice of growing embryos for transfer. Beresford Buttery commenced scanning our patients to monitor follicular growth, using transabdominal approach with a full bladder. Peter Renou joined the team and designed Teflon lined needles to laminar flow, and a much higher oocvte retrieval rate.⁵ By using stimulated cycles and better equipment – including a soft embryo transfer catheter – during 1980, we achieved 18 pregnancies, resulting in nine births, all conceived at St Andrews Hospital, but delivered at the Queen Victoria Medical Centre.⁶

The first baby delivered from such a stimulated cycle, by Beresford Buttery, was 'Baby Victoria', who remained anonymous, born just after the Labour Day weekend. The story, including a photo of John Leeton, only made page six of the *Herald* on 14 March 1981, and is also on view in the College Museum.

The demand on patients was tremendous. They had to stay in hospital for ten to 14 Table 1. IVF pregnancy rates.

	1979	1980	1981	1982	1983	1984			
Laparoscopies	28	136	223	407	518	607			
Patients with oocytes									
Transfers									
Pregnancies	0	18	22	52	74	95			
Rate per laparoscopy		13.2	9.9	12.8	14.3	15.7			
Rate per transfer					16.9	18			

days, be monitored three hourly around the clock, undergo a prolonged laparoscopy and, after embryo transfer, spend 24 hours flat on their backs not moving, using bed pans and having a liquid diet, all for a procedure with a very low chance of success. Fortunately, the pregnancy rate rose from about ten per cent to 15 pre cent over five years. In 2013, the average IVF success rates in Australia for a fresh embryo transfer leading to a live birth varied from 39.4 per cent for women under 30 years of age using their own eggs to 9.2 per cent for women aged from 40-44 using their own eggs.⁷ Monash IVF results 1979 to 1984 are shown in Table 1. A number of world firsts followed, including the world's first IVF twins, which made the front page of the *Herald* on the 6 June 1981, together with a photo of the proud grandparents! This again can be viewed in the Museum at College House.

In 1983, the Monash team achieved and delivered the world's first human frozen embryo IVF pregnancy and the birth was written up as a feature in *New Idea* on 21 April 1984. A copy of the front page is displayed in the Museum.

The Melbourne teams were visited by many international scientists and clinicians,



Figure 2. A selection of just some of the newspaper stories held by the College Museum – many of which are on display.

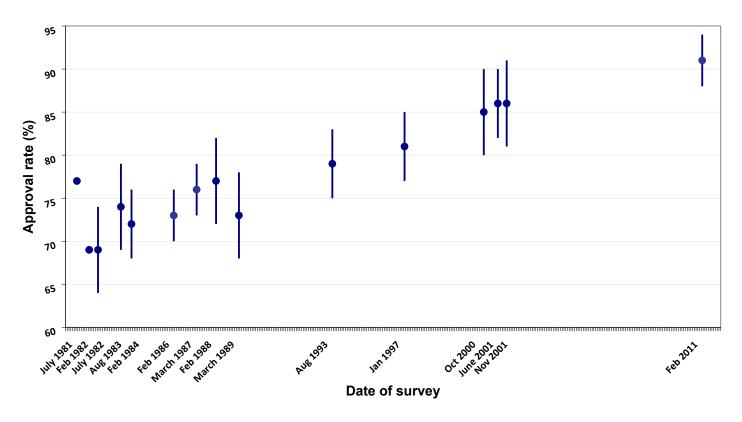


Figure 3. Community support for IVF, surveyed over time.⁹ Reproduced with permission.

including Ed Worthem from Norfolk, Virginia, who was the scientist in the team led by Howard Jones that achieved the first IVF birth in the US in December 1981. Jones graciously acknowledged the help from the two Melbourne teams in his report of their pregnancies.

In 1982 we organised the first IVF workshop in the world, attended by 43 registrants who had come from every continent. The attendees included Andre van Steirteghem, who led the team that revolutionised insemination by developing intra-cytoplasmic sperm injection. We thought we were very entrepreneurial, charging a registration fee of \$500 for the 14-day, hands-on course. I compare this to the one-day business management workshops now held with a \$3000 registration fee!

Although IVF was originally developed to treat women with blocked tubes, male subfertility became a major part of the program. It became apparent that many men who could not impregnate their wives naturally had sufficient sperm to fertilise their eggs in vitro. The 'male factor' group was established with David DeKretser as the andrologist; Chris Yates, scientist and PhD student; Jillian McDonald as the IVF nurse; and myself as the IVF clinician coordinator. Various sperm preparations were tried, including percoll and microdrops, to get a better sperm sample. Peter Temple-Smith, anatomist and scientist, and Graeme Southwick, plastics microsurgeon, joined and the group and helped achieve the world first birth from surgically recovered sperm from the epididymis of a man who had a previous vasectomy: Baby Joseph.

Concurrently, Alan Trounson and Geoff Mann were experimenting with microinjection of sperm under the zona pellucida (subzonal sperm injection [SUZI]). After attempting the technique on a couple, the Victorian Health Minister at the time, Ms Caroline Hogg, instructed the team not to continue with the technique. SC Ng who was working at Monash University with Mann and Trounson, returned to Singapore, and achieved the first human pregnancy and birth with SUZI using the Monash Technique in 1988 at the University of Singapore.⁸

Other techniques that were pioneered under Alan Trounson and Carl Wood's directorships were in vitro maturation of oocytes and blastocyst culture. The team made a significant contribution to the technique of embryo biopsy and fluorescent in situ hybridsation (FISH) for pre-implantation genetic diagnosis (PGD). Leanda Wilton was part of the team developing the technique and subsequently was a member of the Hammersmith Group, under Robert Winston and Alan Handyside, that produced the world's first PGD pregnancy.

Other developments at Monash IVF included the application of the microinjection fallopian transfer (MIFT), where oocytes were injected with sperm and then replaced laparoscopically into the fallopian tubes. This technique soon became obsolete.

Although there was general enthusiasm from the public about Australia leading the world, there was also vocal opposition from some parts of the community, especially the Catholic Church and feminists. In order to assess attitudes, a number of Community Gallop Polls were undertaken by Morgan Gallop Polls. A summary of the approval rates from 12 polls over a 30-year period were published in ANZJOG.⁹ This shows that after initial enthusiasm, with 77 per cent of the community supporting IVF, the controversy about embryo freezing, donation and biopsy resulted in a decline of support, followed by a steady recovery with IVF becoming more common and accepted. Current support for IVF to help sub-fertile couples is well over 90 per cent (see

Figure 3). This is fortunate as nearly four per cent of babies born in Australia today were conceived by IVF.

The whole process has changed dramatically. With use of GnRH agonists, and later antagonists, ovulation can be controlled, monitoring minimised, and, if needed, cycles can be programmed for the approximate day with the use of oral contraceptives and oocyte collections scheduled for convenient hours. Women only have to attend one or maybe two ultrasounds, many units have abandoned hormone assays and oocyte collection is performed as a short-stay procedure by transvaginal ultrasound-auided aspiration with minimal sedation. The transfer of just a single embryo has become almost routine and we no longer see the obstetric disasters of multiple pregnancies.

IVF is now not only used for treatment of subfertility, but also for the elimination of genetic diseases, where pre-implantation genetic diagnosis can be undertaken and embryos shown to be affected not replaced. It has a place in fertility preservation for women undergoing chemotherapy or radiotherapy, either by standard IVF and oocyte or embryo preservation, or by the technique of ovarian tissue cryopreservation with auto transplantation and subsequent IVF. Its role in social fertility preservation is still debatable, but the technique is now widely practised around the world.

What started as an innovative hypothesis in the 1970s has now become an everyday clinical treatment available not only in every capital city in Australia, but also at many regional centres.

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RANZCOG 2016 ANNUAL SCIENTIFIC MEETING

EAST MEETS WEST

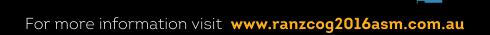
Diplomates Days

The RANZCOG 2016 Annual Scientific Meeting (ASM) will be held in Perth, Western Australia, in October 2016.

The ASM promises to be a diverse educational and enriching collegiate experience covering a wide variety of topics. Diplomates Days will be held preceding the main Meeting on Saturday 15 and Sunday 16 October 2016; participant numbers will be limited, so save the dates now. Register online now to avoid disappointment! Preliminary topics include:

Day 1 - Obstetrics:CTGs, Expert Panel on Pre-term Birth, Obesity - BMI Measurement in Pregnancy, Placental
Conditions & Pre-eclampsia.

Day 2 - Gynaecology: Cervical Screening/HPV, Medical Management of Transgender, Expert Panel on Contraception, Polycystic Ovary Syndrome & Urogynaecology.



ART: fertile ground for reporters



A/Prof Anusch Yazdani FRANZCOG, CREI

Fertility and assisted reproductive technology (ART) frequently feature in the tabloid press, competing for space with the Kardashians and advertisements for breakfast television. It is a testament to the universal experience of reproduction – mixed with a good dose of pioneering medical science at the boundaries of ethics and fuelled by commercial interests – that this subject continues to dominate the headlines. This review takes a pragmatic approach to the stories that have caught the headlines in last few decades, selecting specific topics that have captured the public imagination.

The good

Louise Brown, the first live birth conceived by IVF, was born on 25 July 1978, by planned caesarean section in Oldham, UK. It will come to no surprise to anyone who has worked in the UK that she was delivered by the registrar, John Webster, who was, unfortunately, largely forgotten in the most-featured medical story of the decade. Instead, Patrick Steptoe and Robert Edwards, as the 'fathers' of in vitro fertilisation (IVF), dominated the front page of every regional paper, including the front covers of Life and Time magazines. Edwards was eventually awarded the 2010 Nobel Prize in Medicine for his work. Of course, this achievement was the culmination of decades of scientific discovery and multiple teams around the world were racing to publication. By the mid-70s, the Americans had been pushed out of the race and the British and Australian teams were fighting for a breakthrough. The Australian team, led by Carl Wood, had taken the lead with the publication of the first pregnancy which, unfortunately, resulted in an early miscarriage. While that crucial first live birth eluded them, Australia pioneered modern IVF (see p26).

It is not surprising that with such high stakes, the British teams managed their relationship with the media very carefully. Publications were short, directed and followed by controlled press conferences. Information surrounding the pregnancy was tightly guarded and the Brown family signed an exclusivity deal with the Daily Mail, which managed the build up to the delivery. Lesley Brown was booked into the hospital under a pseudonym and the birth was filmed by the Central Office of Information in secrecy to manage the media and competing commercial interests. In this setting, it would have been expected that such a momentous occasion would be celebrated by a landmark paper, rather than a mere Letter to the Editor. To the chagrin of the protagonists, such was the suspicion of commercial gain before scientific rigour, that the Chicagobased fertility research organisation, the Barren Foundation, cancelled their award presentation to Patrick Steptoe.

Male factor infertility remained the great

challenge of assisted reproduction until the introduction of intracytoplasmic sperm injection (ICSI), a technique that evolved from subzonal insemination (SUZI). ICSI has become the face of IVF: the image of the micromanipulated oocyte at the time of sperm injection, with its subtle but unmistakable symbolism, has become the posterchild of modern reproduction. Following in the footprints of Steptoe and Edwards, this breakthrough was again announced with little more than a Short Report in the Lancet by Gianpiero Palermo from the Center for Reproductive Medicine in Brussels, headed by Paul Devroey and Andre Van Steirteghem. Reportedly, the first embryo was produced in 1990 and the first baby was born in January 1992. Embryologists have always argued that the technique evolved more by accident than design, as scientists were inadvertently entering the ooplasm during the procedure, which would certainly account for the publication delay.

The controversial

Reproduction at any cost Assisted reproduction has the capacity to achieve conception in situations beyond natural reproduction, and this is nowhere more evident than with extreme reproductive assistance.

The oldest mother

Maria del Carmen Bousada de Lara made headlines around the world when her twins were delivered by caesarean section in Barcelona, Spain, in December 2006, one week before her 67th birthday. The case made headlines for a number of reasons: Maria had attended a fertility clinic, claiming to be 55 years of age and had sold her house to raise the reported US \$59 000 to pay for fertility treatment in the US. Her family was unaware she had gone overseas for fertility treatment and publicly criticised her decision. Despite her hopes that she would live to 101, like her own mother, and be able to raise her family, she died in 2009 from gastric cancer.

Two years later, Rajo Devi became the verified oldest woman to give birth to a singleton female on 29 November 2008, though Omkari Panwar has been claimed to be the oldest mother after the birth of twins, in July 2008. As she has no birth certificate, sources have variably estimated her age between 70 and 72 at the time of the birth.

In Australia and New Zealand, fertility units set their own age limits for assisted reproduction, though most would limit treatment to the time of expected

have used ICSI to treat cause of severely impaired

in whom IVF and SUZI of a single spermatozoon lone in 47 metaphase-II ined intact after injection, 15 embryos were replaced ies occurred after eight singleton and one twin cal abortion. Two healthy

denvered from the singleton pregnancies and a healthy boy and girl from the twin pregnancy.

Pregnancies after intracytoplasmic

injection of single spermatozoon

into an oocyte

GIANPIERO PALERMO HUBERT JORIS

acytoplasmic sperm injection (ICSI) is a

sing assisted-fertilisation technique that may

ANDRE C. VAN STEIRTEGHEM

we not become pregnant by

or subzonal insemination

Lancet 1992; 340: 17-18.

Letters to the Editor

BIRTH AFTER THE REIMPLANTATION OF A HUMAN EMBRYO

SIR,-We wish to report that one of our patients, a 30-yearold nulliparous married woman, was safely delivered by cæsarean section on July 25, 1978, of a normal healthy infant girl weighing 2700 g. The patient had been referred to one of us (P.C.S.) in 1976 with a history of 9 years' infertility, tubal occlusions, and unsuccessful salpingostomies done in 1970 with

excision of the ampullæ of both oviducts tubal blockages. Laparoscopy in Febr grossly distorted tubal remnants with or and ovarian adhesions. Laparotomy in A with excision of the remains of both th suspension of the ovaries in good position

Pregnancy was established after lapare oocyte on Nov. 10, 1977, in-vitro fertilisa vage in culture media, and the reimpla embryo into the uterus $2\frac{1}{2}$ days later. weeks' pregnancy revealed normal a-feto chromosome abnormalities in a 46 XX delivery the mother was 38 weeks and 5 last menstrual period, and she had pr Blood-pressure was fluctuating around volved both legs up to knee level togeth back, hands, and face; the blood-uric-aci albumin 0.5 g/l of urine. Ultrasonic graphic appearances showed that the fe for several weeks from week 30. Blood placental lactogen levels also dropped be during this period. However, the fetus g ing the last 10 days before delivery wh improved greatly. On the day of delive meter had reached 9.6 cm, and 5 ml removed safely under sonic control. The lin ratio was 3.9:1, indicative of maturity respiratory-distress syndrome.

We hope to publish further medical and scientific details in your columns at a later date.

Department of Obstetrics and Gynæcology, General Hospital, Oldham OL1 2JH University Physiology Laboratory, Cambridge CB2 3EG

menopause. In Australia, one in four

are now over the age of 40. In 2013,

in 21 pregnancies and 11 live births.

initiated in recipients over the age of

45, resulting in 142 pregnancies and

101 live births. Consequently, as the

the risks of pregnancy over the age

of 45 have become more clear: not

morbidity increases in proportion with

experience with conception in women of

unexpectedly, maternal, fetal and neonatal

maternal age. Unfortunately, the absence

of chronic disease, such as a pre-existing

hypertensive disorder, is not predictive of

Statement C-Obs 52, which advises that

a better maternal or neonatal outcome

or significant morbidity. This issue was

women over the age of 45 attempting

specifically addressed in RANZCOG

very advanced maternal age increases,

Similarly, there were 575 donor cycles

there were 903 autologous fresh cycles in women over the age of 45, resulting

women accessing reproductive assistance

conception be referred for medical review prior to conception.

The highest number of multiple pregnancies

Nadya Suleman made headlines in 2009 with the delivery of octuplets in January. The medical board of California discovered that the pregnancy resulted from the transfer of 12 blastocysts in a fresh IVF cycle by her treating physician, whose licence was revoked in July 2011. The children were delivered by a team of 46 physicians in a remarkable feat of feto-maternal and neonatal medicine. Nadya's story had all the makings of a headline: at first glance, a seemingly unassuming, average individual, hit by misfortune. Digging deeper, the story revealed a scandalous past, an existing family of six children, a donor conception, public funding and a high-profile medical practitioner, just waiting to be taken down. An instant celebrity was born and she featured in an estimated half million news

reports, tweets and social media instances. Fortunately, the peculiarly US-based practice of multifetal transfers is now an anachronism in Australia and New Zealand (see p34).

Three-party reproduction

Advances in embryonic and genomic manipulation have paved the way not only for reproduction, but also for improvement. While no pregnancies have been reported from human nuclear genetic engineering, the UK hit world headlines by legalising three-party assisted reproduction. Seemingly speaking from the heart of IVF specialists worldwide, Lord Robert Winston declared to the House of Lords in 2015: 'We do not try to supplant God. We try to augment his works.'

A number of mitochondrial disorders, such as the muscular dystrophies, are related to mutations in extranuclear mitochondrial DNA and are therefore almost entirely

Making headlines



P. C. STEPTOE

R. G. EDWARDS Short reports in the medical literature, but major coverage in the lay press: the paradox of ART breakthroughs.



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Baby Gammy: Biological father David Farnell tries to access donations raised for child's medical costs

Updated 19 May 2015, 1:45pr

The biological father of Gammy, the baby at the centre of a surrogacy dispute last year, is trying to access donations raised for the child's medical costs, a charity says.

The case made international headlines last year after convicted sex offender David Farnell and his wife Wendy Li abandoned their son in Thailand because he has Down syndrome and took only his twin sister back to Australia.



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World's oldest mother dies, leaving her two-year-old twin sons orphaned

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Spanish woman thought to have been diagnosed with cancer after giving birth Health Editor. Jeremy Laurance | Thursday 16 July 2009| CO comments



She was the world's oldest mother when she gave birth to twin boys at the age of 66 on 29 December 2006. Less than three years on, Maria del Carmen Bousada de Lara has died, her family announced vesterday.

The former shopworker, who travelled from her home in Spain to

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Britain's House of Lords approves conception of three-person babies

Clinics in UK will be able to apply for licenses from this autumn after MPs approved new rules earlier this month



IVF industry criticised for 'misleading claims, aggressive marketing'

7.30 By Madeleine Morris Updated Tue at 8:57pm

Insiders in the IVF industry have criticised clinics for using misleading claims and aggressive marketing in the increasingly cutthroat, multi-million dollar sector.

Consumer watchdog the ACCC is currently reviewing dozens of IVF clinics amid mounting complaints about the lack of transparency of IVF



Just because you can, doesn't mean you should: the ethical implications of scientific advances play out across the pages of the world's media.

maternally inherited. Cytoplasmic transfer, supplementing the ooplasm with unaffected mitochondria, has been described and the first child born after cytoplasmic transfer in 1997. However, the effect of such procedures is limited and more advanced techniques, such as pronuclear or spindle transfer effectively relocate the nuclear material into a third-party oocyte. Legislative changes, as passed in the UK, will empower IVF clinics to create genetically engineered humans, that represents a breakthrough for families afflicted by disorders such as muscular dystrophy.

The ugly

Crossborder reproductive care and surrogacy

In 2014, the abandonment of baby Gammy made international headlines when a convicted sex offender, David Farnell, and his wife commissioned a surrogacy in Thailand. When Gammy was diagnosed with Down syndrome, Farnell returned only with his unaffected twin sister. The case highlighted the difficulties associated with 'reproductive tourism', as it became known in the popular press. The case highlighted the desperation of couples suffering from infertility and, in response, the College is developing a statement on cross-border reproductive care and surrogacy.

Transparency

In an increasingly competitive market, no radio broadcast is complete without an advertisement for yet another IVF service. It is not surprising that in such an environment, patients are looking for comparators to select their provider. At first glance, price and success rates appear to be the obvious solution. Unfortunately, the recent Australian Competition and Consumer Commission inquiry highlights the problem of presenting IVF success rates. At the most fundamental level, the definition of a pregnancy is obvious, unless you are running an IVF unit. Pregnancies have been variably defined at the point of a positive pregnancy test (usually two weeks after an egg pick up), an appropriate sequential rise in hCG, an ultrasound scan demonstrating a viable pregnancy at seven or 12 weeks, a gestation beyond 20 weeks or, most

convincingly, with the delivery of a live birth. Even if a specific definition is accepted as an appropriate numerator, IVF clinics still face the challenge of how to report the pregnancy rate: should the denominator be the number of patients commencing a cycle, those progressing to an egg pick up, proceeding to transfer or the number of embryos transferred? If specialists cannot agree on uniform reporting, this issue is even more complicated for the lay public. A published pregnancy rate of 25 per cent for a blastocyst transfer in a 43-year-old is meaningless unless the patient is aware that the majority will not reach this stage and there is a high pregnancy loss thereafter. More concerning is the inevitable request to rank clinics or, worse, practitioners, which will inevitably result in those patients who most require our help to be least likely to receive treatment.

Conclusion

Looking back on almost 40 years of headlines, the profession can be filled with a sense of pride at the incredible vision, achievement and ground-breaking treatment that has occurred in this specialty. However, with achievement and controversy also comes the realisation that progress cannot proceed unmonitored and, at times, has unexpected consequences. Just like an IVF cycle.

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Family Criticizes 67-Year-Old Spanish Woman

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Singular success: ART in Australia and New Zealand



Prof Robert J Norman AO MD, MBChB (Hons), FRANZCOG, FRCPA, CREI, FAHMS Professor of Reproductive and Periconceptual medicine Robinson Research Institute, University of Adelaide Medical Director FertilitySA

In 2009, media reports emerged regarding Nadya Suleman, a woman in the US who had become pregnant following the transfer of 12 embryos and had eight fetuses who were subsequently delivered. This highlighted the dangerous practices in the US IVF industry, where multiple embryos were transferred. This still continues today as evidenced by the SART Database, which publishes the activity and success rates of every registered USA clinic. Worldwide, transfer of multiple embryos following IVF is the norm as clinics seek a competitive advantage in providing high pregnancy rates. Even in the UK, elective single embryo transfer is rare. There is no country in continental Asia, Africa or South America that replaces only one embryo electively and multiple pregnancy rates are routinely above 20 per cent, with the attendant complications known to all obstetricians.

The maternal and fetal complications of a multiple pregnancy following IVF have been well documented (but appear to be no worse than those of spontaneously conceived multiples, providing they are not monozygous). However, unlike naturally occurring multiples, the occurrence of multiple pregnancies in IVF is largely preventable. Even the occurrence of a single baby after transferring multiple embryos is not the best outcome: the perinatal mortality of a singleton conceived after double embryo transfer is higher than a singleton conceived after single embryo transfer.¹

In Australia and New Zealand and parts of Europe, including Scandinavia, Belgium and the Netherlands, single embryo transfer has been advocated for more than a decade and encouraged through regulation, accreditation and education. Why is there such a contrast between areas of the world with equally high medical care? What have we done right in our RANZCOG community that others have not achieved?

One of the great differences between medicine in the US compared to those domains that practice high levels of single embryo transfer is the funding by the state for assisted reproduction. In Australia and New Zealand, there is significant Federal funding for IVF cycles, which substantially reduces the cost to the patient of going through this treatment. This encourages patients to take fewer risks because if they do not become pregnant on a single embryo transfer, they can use the frozen embryos on subsequent cycles without exorbitant expense. Even in New Zealand, which is not quite as generous in its funding as Australia, there is a very high degree of single embryo transfer. Various countries in Europe also mandate single embryo transfer as a condition for generous publicly funded

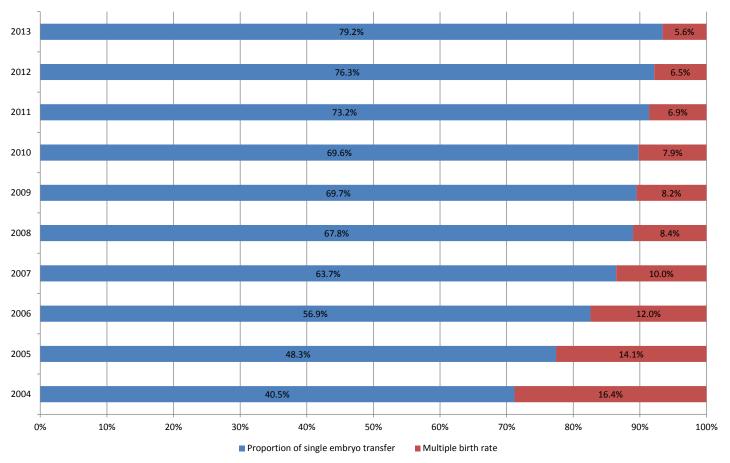
cycles. There is now abundant evidence that transferring embryos singly does not compromise the overall pregnancy rate, while reducing multiple pregnancy rates to very low levels.²

A second reason for the high prevalence of single embryo transfer in key countries has been the advocacy by professional groups to educate patients and to encourage practitioners to practice single embryo transfer. In the 1990s, clinics in Sydney and Adelaide started to do single embryo transfer electively and a randomised control trial, the Asset Study, conducted across several clinics led to information that increasingly persuaded patients that double embryo transfer was not safe for them. The rapid change from double to single embryo transfer occurred in the absence of any regulation or coercion from government authorities and was voluntarily incorporated into the RTAC guidelines by which clinics are accredited. It is now impossible for patients to shop around to find a clinic that will give them two embryos when all the others are offering a single embryo transfer.

The multiple pregnancy rate now is below six per cent in Australia, which is remarkable and is only equalled by Sweden (see Figure 1). This is aided by the increasing success of freezing embryos and their excellent, sometimes superior, pregnancy rates compared with fresh embryo transfer. This has led to an increased confidence in encouraging patients to accept single embryo transfer, even at later ages, knowing that the pregnancy rates for the cohort of embryos after using them all will be the same regardless of single versus multiple transfer, but with a very small multiple rate if single transfer occurs.

Several problems remain, however. The first is the problem of the older woman in whom implantation rates for an embryo are considerably reduced, owing to aneuploidy of the embryo. The common practice has been to offer a double embryo transfer to patients who are older than 38, with a maximum of three for women over 40, although this rarely occurs. This has led to unexpected multiple pregnancy rates in women where implantation rates are generally low. Similarly, double embryo transfer is sometimes practised when several transfers have occurred in younger women and again a multiple pregnancy can emerge unexpectedly.

Approaches to this problem generally run along two lines. The first is to always offer one embryo transfer regardless of



Proportion of SET & multiple birth rate following fresh and thaw embryo transfers, Australia and New Zealand, 2004-2013

Figure 1. Reduction in IVF multiple pregnancy delivery rates in Australia and New Zealand (ANZARD data, courtesy Dr Georgina Chambers, UNSW).

age, bearing in mind that other embryos can be stored and used on a single embryo transfer in subsequent cycles. This, however, leads to frustration and increased expense for patients who are putting back embryos that may be aneuploid without any success. The second approach has become more popular recently and that is to do preimplantation genetic diagnosis on embryos from older women to identify those that are euploid and to only replace those singly. This is now becoming common practice in the US, where the resistance to single embryo transfer has disappeared with the advent of good preimplantation genetic screening services in every clinic. Indeed, many clinics are now going to the extreme of not putting any embryos back fresh, but biopsying all of the embryos before freezing them and then only replacing the euploid on a frozen cycle. Given that freezing is now so good and that frozen cycle implantation rates are as good as fresh, this would appear to be an attractive option. However, despite many thousands of babies born

from preimplantation genetic diagnosis, safety data are lacking and there are very few, if any, randomised control trials that show the benefit of preimplantation genetic screening overall. Given the strong financial incentives in the IVF industry, it may take some time before we get substantial data to show whether it is beneficial or not.

A further problem is of monozygous pregnancies arising from single embryo transfer. These are clearly unpreventable, but have a very high risk of pregnancy complications. There has been a suggestion these are more common after blastocyst culture and transfer and it is possible that early transfer, such as at cleavage stage, may work better. However, selection of a superior embryo for implantation is more difficult at this stage. New technologies - such as metabolomics of the culture media, continuous imaging of the embryo development and evaluation of microRNA from the embryo - remain to be shown to be valuable.

Other problems remain in reproductive medicine relating to multiple pregnancy. Ovulation induction with clomiphene, letrozole and follicle stimulating hormone (FSH) is still widely practised and unless monitored carefully, can lead to multiple ovulations and increased multiple pregnancy rates. The practice of intrauterine insemination (IUI) using FSH is still used in Australia and there have been several well-publicised cases of women producing more than one fetus on IUI, including one woman who had ten children in two IUI and one IVF pregnancies. In the strong belief that multiple pregnancies are not ideal, many practitioners have virtually abandoned ovulation induction to use IVF, which they believe is better for their patient in terms of speed and reducing the multiple pregnancy rate and, at the same time, is more financially advantageous for clinics. This has led to underskilling of our new trainees in reproductive medicine in ovulation induction, leading to earlier use of IVF than is required if an experienced practitioner had used monitored oral

TIME

Like 1



Read Later

Dr. Michael Kamrava, 57, leaves his Beverly Hills office.

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The Fertility Doctor Behind the "Octomom"

By Alison Stateman / Los Angeles | Saturday, Mar. 07, 2009

To Nadva Suleman, Dr. Michael Kamrava was a hero. Suleman sought treatment at Kamrava's West Coast IVF Clinic, in order to conceive all 14 of her children the last batch of whom generated worldwide headlines as only the second living set of octuplets born in the United States. However, to other fertility practitioners and professional reproductive associations, Kamrava's reported means were troubling. And at least one former client had little heroic to say

Tweet

"I didn't like him at all. He was very rude," says Michael Verdi, 59, who, with his late wife Eva Menen, went to Kamrava in the early 1990s for infertility treatment. (Menen died of an unrelated illness in

1998.) "When the treatment started, I was asking him questions and I wouldn't get proper answers. I would get psychiatric answers, clinical answers." After three months without success, the couple stopped treatment. "Eva was getting emotionally upset because nothing was happening and he wasn't explaining things," says Verdi. "We did research and figured out he was doing a lot of stuff wrong. He overmedicated her and he was doing insemination when she

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Birth of Octuplets Stirs Ethical Concerns

By Ashley Surdin Washington Post Staff Writer Wednesday, February 4, 2009

LOS ANGELES, Feb. 3 -- Public opinion seems to be cresting against her, her own mother is rattled, and now fertility experts are suggesting the case of Nadya Suleman and her octuplets constitutes a breach of medical guidelines.



Suleman, 33, gave birth to six boys and two girls by

Caesarean section Jan. 26 at a Kaiser Permanente Medical Center in Bellflower, Calif. The miraculous event -- reportedly one of only two live octuplet births ever in the United States - quickly drew criticism after it was revealed that Suleman is single, unemployed, lives with her mother and already has six children -- including twins -- ranging in age from 2 to 7.

Her daughter "is not evil, but she is obsessed with children. She loves children, she is very good with children, but obviously, she overdid herself," her mother, Angela Suleman, told the Los Angeles Times. She decided to have more embryos implanted in hopes of having "just one more girl."

"And look what happened. Octuplets. Dear God."

Responses to the 'Octomom' news ran the gamut: from academic papers and political discussion to salacious stories, and pictures, in the gutter press.

drugs or gonadotrophins instead. Most experienced practitioners of FSH ovulation induction report multiple pregnancies to be around the rates of single embryo IVF.³

Australia and New Zealand have led the way in the world in responsible practises in IVF, particularly relating to the use of single embryos. Any unravelling of the financial incentives for patients to practice this will

lead to a rise in multiple pregnancy rate and corresponding implications for health costs and safety.

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nd Sociological Responsibilities: "Octomom" as a Case of Fertility Treatments

Manninen, J Clinic Res Bioeth 2011, S:1 /10.4172/2155-9627.S1

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http://dx.doi.org

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elopment of various forms of fertility treatments has made the dream of parenthood concrete elopine to various tothis of retring versions as indue the user of partitudoe contention of an enhances, fertility misused. Although stall on an odes of conception. Yet, like many scientific advances, fertility misused. Although still rare compared to the birth of singletons, the number of triplets, gher-order multiple births have quadrupped in the past thirty years in the United States, mostly revalent use of fertility treatments. In contrast, the number of multiple births has decreased in even though 54% of all assistant reproductive technology cycles take place in Europe, most Idelines have been implemented throughout several countries general towards reducing the left multiple births.¹ The gestation of multiple fetuses can result in dire consequences for them. stilloorn, or die shortly after birth. When they do survive, they are often born prematurely and ind may suffer from a lifetime of physical or developmental impairments.

paper is to explore the moral dimensions of certain uses of fertility treatments in light of the result forn higher-order multiple births. I will do this by mainly focusing on the now infamous also known as "Octomom." I argue that Suleman and her fertility physician, Michael Kamrava, Juties and virtues in the creation of her octuplets, but that my criticism of their actions equally uestionable uses of reproductive technology. Moreover, I will show that the responsibility for order multiple births falls on the shoulders of not only patients and their doctors, but also the *islains* in general, insurance companies, and even the media.

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Suleman's case provides an avenue to begin an honest discussion concerning a problematic trend: the increasing instances of higherorder multiple births (a pregnancy containing three or more fetuses; hereon in HOMB) in the U.S. as a result of the use of assisted reproductive technology (ART). The United States' 2007 National Vital Statistics Report shows that the twin birth rate increased 70% between

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Creation of a controversy: stem cell science

Prof William Ledger MA, DPhil, BM, BCh, FRCOG, FRANZCOG, CREI Head and Professor of the Discipline of Obstetrics & Gynaecology School of Women's & Children's Health, UNSW

I was a pre-clinical medical student in 1978 when Louise Brown's birth after IVF hit the headlines. The early days of IVF were highly newsworthy and every week had a story either over-dramatising the latest great breakthrough or threatening the end of civilisation as we know it, owing to the nefarious activities of these dangerous doctors. Maybe this was why I became interested in this area of obstetrics and gynaecology, although it was only much later, in Edinburgh in 1987, that I committed to subspecialisation in the new field of 'reproductive medicine'. My clinical training in management of infertility and the plethora of other endocrine and anatomic disorders that affect the human reproductive system could not have been at a more exciting time as IVF came of age and the opportunities that access to human embryonic tissue could offer became obvious.

I moved to take the Chair in Obstetrics and Gynaecology in Sheffield in 1999. I continued to have an active interest in obstetrics and was regularly 'on call' for the labour ward at the Jessop Hospital, but was mainly occupied in managing the move to the academic department that was part of the new 'Jessop Wing' that opened in 2001 (a note to developers of new hospitals: it's not wise to use the same, or a similar, name as the old building – people show up in the wrong place even years later). A small group of us were asked to consider setting up an National Health Service (NHS)-based fertility/IVF centre within the new building. At this time many IVF units were entirely private, limiting access to the less well off, and NHS funding was extremely patchy. We felt strongly that Sheffield needed an NHS centre and were fortunate to have access to space and funding to set this up. From the outset we had a strong academic presence within the clinical unit, with a senior lecturer, clinical lecturer and non-clinical senior lecturer (now professor) and myself working in the Assisted Conception Unit (ACU). We were approached at an early stage by Profs Harry Moore and Peter Andrews, both University of Sheffield biomedical researchers, who were keen to develop studies using human embryonic stem cells (hESC). This was timely as Tony Blair was piloting the necessary legislation through the UK Parliament to legalise hESC research and possible clinical use. Our new unit gave us the opportunity

to develop 'near GMP' IVF. This meant that hESC products could potentially be used in clinical trials and therapeutics later.

Good manufacturing practice (GMP) is used in the pharmaceutical industry for drug development and clinical trial development. It requires clean room technology with intensive monitoring of air guality, bacteriological contamination and facility monitoring, for example of incubator temperature, humidity, O₂ and CO₂ tension and so forth. We were able to build these features into the IVF unit with a grant from the Medical Research Council. This also allowed us to meet the requirements of the European Union Cells and Tissues Directive, which was being applied to UK IVF at that time. We were one of the first centres to meet these criteria.

We had to call this 'near GMP' because it is impossible to carry out some of the IVF procedures to a GMP standard. The mechanics of sperm sample production were particularly difficult to organise in a completely sterile controlled environment as it put many of the men off their stroke. However, there was optimism that we could derive stem cell lines in the new ACU that could be used later in clinical trials.

Once the House of Lords approved the Act of Parliament we were able to apply for ethics committee permission to try to derive hESC. We were always careful to make sure that every step of the process was fully approved and were transparent in our plans in setting up the stem cell lab within the IVF lab. Harry and Peter were able to collaborate with the clinical team and derived stable stem cell lines that



Newspaper cartoonists in the USA found much to inspire them in the stem cell debate. © Jimmy Margulies. First appeared in The Record, Hackensack, New Jersey. Used with permission of the artist.

were later donated to the national Stem Cell Bank run by National Institute for **Biological Standards and Control (NIBSC)** in North London, which opened in 2004. This allowed any legitimate researchers to have access to the cell lines. At that time, Prof Colin Blakemore, chief executive of the MRC, said: 'Stem cell research offers real promise for the treatment of currently incurable diseases. The bank will ensure that researchers can explore the enormous potential of this exciting science for the future benefit of patients.' This describes the feeling that many of us had about the potential benefits that could derive from hESC research.

There were many early achievements and discoveries. I remember the excitement when the lab identified a stem cell derivative that secreted insulin and modified its level of secretion in response to changing glucose concentration in the culture medium. There was a finding that some lines de-differentiated even after many passages, becoming teratomas, with obvious implications for human therapeutic use, and the persistent problem that the cell lines expressed HLA and hence could not be used for transplantation to other individuals. There was also constant engagement with the HFEA as regulator of this research, with MRC and NIBSC and with the public concerning the ethics and governance of hESC research. I think we expected more criticism and debate than actually happened, and we were never picketed or heckled. Of course, this was before the days of social media, so those who wished to complain and criticise were identifiable and could not anonymously troll.

Stem cell research and therapeutics has come a long way in the last decade. Many of us have moved on to other areas of work and maybe the promise of the early days has yet to be realised. However, there are already tangible clinical benefits from this



research and it has begun to translate into clinical practice. We have also learned a great deal about cell biology, regulation of cell division and differentiation and about early embryology. The ACU in Sheffield has become highly successful and continues to be active in research. The world of IVF also continues to innovate and adopt new ideas at a rapid rate. The use of IVF to access the embryonic genome will be a key tool in the science of individualised medicine in the coming decades. There are many more discoveries to make!

Further reading

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Steering Committee for the UK Stem Cell Bank and for the use of Stem Cell Lines. See: www.mrc. ac.uk/research/research-policy-ethics/uk-stemcell-bank-steering-committee/.

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Meanwhile, in Australia and the UK, the possibilities of this scientific breakthrough were the focus of positive news reports.

unday Age 26 August 2012

Mont Liggins: an obstetrical scientist with a lasting impact factor

Prof Sir Peter Gluckman

ONZ, KNZM, FRANZCOG (Hon), FRCPCH, FRACP, FMedSci, FRSNZ, FRS Chief Science Advisor to the Prime Minister of New Zealand University Distinguished Professor Liggins Institute, University of Auckland

In 1972, Mont Liggins from National Women's Hospital in Auckland, and his neonatologist colleague, Ross Howie, published a paper in Pediatrics that fundamentally changed the face of modern perinatology.¹ They reported that mothers who were in premature labour and who were given antenatal betamethasone delivered children who had a significantly reduced risk of respiratory distress syndrome or hyaline membrane disease. At that time, immaturity of lung function was the primary concern of the emerging field of neonatology; respiratory care was in its infancy and survival rates for infants below 34 weeks of gestation were rather low. This finding was to dramatically change clinical perinatology.

Liggins was born in 1926 in a small provincial town near Auckland. His preferred name, Mont, came from a cartoon character that he had been immensely fond of as a little boy and no one called him by his proper name. He had graduated from medical school in Otago in 1949, and then trained in Newcastle on Tyne in obstetrics and gynaecology. He and soon-to-be his wife, Celia (1928–2003), met while applying for the same post and, fortunately, they were both appointed. In 1959 they returned to Auckland, Celia to enter private practice and Mont to join the fledging academic unit at National Women's Hospital in Auckland. Here there was another soon-to-be hero of translational obstetrics, Bill (later Sir William) Liley, who was conducting studies that led him to undertake the first successful intrauterine intraperitoneal transfusions of blood to treat fetal haemolytic anaemia caused by Rh incompatibility. Liggins worked with Liley on these early studies and, with his characteristic inventiveness, developed a self-retaining catheter for use in pregnant sheep² – an experimental system that Mont was to use to launch a remarkable career.

Liggins decided to focus his own career on what he then saw as, and still remains, the biggest challenge in obstetrics: premature labour. He took his cue from observations that cows with hereditary pituitary dysplasia had prolonged pregnancies. At the University of California at Davis, he studied sheep that also had prolonged gestation as a result of eating a lily containing the alkaloid jervine early in pregnancy. These fetuses were also malformed with hypothalamic and pituitary dysplasias. Liggins returned to New Zealand determined to explore the biology of this relationship experimentally. He developed techniques to remove pituitary or adrenal glands of the sheep fetus and showed that these pregnancies were

prolonged. He then showed that he could reverse this effect, as well as accelerate birth by infusing corticotropin (ACTH) or glucocorticoids into the normal fetus.³

It was a serendipitous observation from this set of studies that was to change the path of neonatology and place Liggins at the forefront of perinatal science of the 20th century. It was already known from US research in the 1960s that the core deficit in hyaline membrane disease (which had killed President John F Kennedy's youngest son, who had been born prematurely in 1963, shortly before JFK's assassination) was a lack of pulmonary surfactant in the fetal alveoli. This lack meant the lungs could not maintain their opening at the end of expiration, so premature lambs died and at postmortem there was no air in their lungs. But in his 1967 studies of infusing the normal fetus with ACTH or cortisol to induce premature birth, Mont noted that a prematurely born lamb had died with air in its lungs.⁴ I suspect this incidental observation would have been ignored by most, but Liggins recognised the significance of this finding. He rapidly changed his emphasis to study the impact of fetal glucocorticoids on the maturation of the fetal lung.

Almost immediately, he launched a robustly designed, double-blind clinical trial of maternal betamethasone to women in premature labour, even though this type of clinical research had not really been part of his past experience. Ross Howie provided the neonatal expertise to assess the infants born in the trial. The results, published in 1972, were compelling, with more than a 50 per cent reduction in perinatal deaths.¹ That study, supported by a number of similar studies that followed in other countries, became represented in the metaanalysis that still features on the Cochrane Collaboration logo. It is amazing to think that less than five years passed between the publication of the initial observation that glucocorticoids induced premature delivery in the sheep to the publication of the clinical trial of antenatal betamethasone. That speed of translation would be most unlikely, if not impossible, today.

While some centres rapidly adopted the use of glucocorticoids, scepticism for research not initiated in the USA meant that it would be another two decades before the American Congress of Obstetricians and Gynecologists was to endorse their use. Their effectiveness, safety and limits have been extensively reported and the original cohort has continued to be studied into the

J. Endoer. (1969), 45, 515-523 With 1 plate Printed in Great Britain

PREMATURE DELIVERY OF FOETAL LAMBS INFUSED WITH GLUCOCORTICOIDS

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(Received 14 April 1969)

SUMMARY

Dexamethasone caused premature delivery when infused into foetal lambs at rates of 0.06-4.0 mg./24 hr. but it had no effect when administered to pregnant ewes at the rate of 4.0 mg./24 hr. Infusions into the foctus of deoxycorticosterone or corticosterone were ineffective; mixtures of dexamethasone and deoxycorticosterone did not cause parturition more rapidly than dexamethesone alone. Thus, the ability of corticosteroids to cause premature parturition appears to depend on glucocorticoid rather than mineralocorticoid activity.

Parturition induced by dexamethasone was not delayed by administration of 100 mg, progesterone/24 hr, to the ewe or to the foetus. This suggests either that withdrawal of inhibitory effects of progesterone on the myometrium can occur independently of the progesterone concentration in peripheral plasma, or that the mechanism of parturition provoked by corticosteroids in the foetus can override any regulatory influence of progesterone on myometrial contractility.

Partial acration of the lungs was observed in lambs born vaginally at 117-123 days of gestation after receiving dexamethasone. It is suggested that this may be the result of accelerated appearance of surfactant activity.

INTRODUCTION

The onset of parturition in the ewe has been shown to be profoundly influenced by the foetus (Liggins, 1968). Destruction of the foetal pituitary or hypothalamus leads to marked prolongation of gestation (Liggins, Kennedy & Holm, 1967) and conversely, stimulation of the foetal adrenals by corticotrophin (ACTH) or infusion of cortisol into the foetus leads to premature parturition (Liggins, 1968). Thus it appears likely that the foetal lamb affects myometrial contractility through a pathway which includes the foetal hypothalamus, pituitary and adrenals, and that the activity of the adrenal cortex in this particular function is mediated by a corticosteroid. However, the means by which a corticosteroid in the foetus may influence the myometrium remains obscure.

Cortisol has both mineralocorticoid and glucocorticoid activity. The present experiments were designed to determine which of these components was responsible Endoc. 45. 4

The title pages of the research papers that were to change the face of perinatology.

fourth decade of life by Prof Jane Harding of the Liggins Institute and her colleagues.

Liggins went on to explore, as did other groups, the mode of action of glucocorticoids on the fetal lung: they induced both surfactant production and changes in lung elasticity. He also explored other aspects of the regulation of fetal lung maturation, particularly the role of fetal thyroid hormones and TRH, as well as the effects of fetal breathing movements. The latter he showed in elegant experiments to promote lung growth.⁵ Indeed, Liggins had played a role in the rediscovery of fetal breathing movements - a phenomenon that had been observed decades earlier, but ignored, and which Liggins rediscovered while on sabbatical with Geoffrey Dawes in Oxford in 1969,

simultaneously with a French group - this area of study would play an important part in the developing science of fetal neurophysiology throughout the 1970s and 1980s.

We now know that the antenatal rise in glucocorticoids is important for the maturation of a wide variety of biological systems in the mammalian fetus. Indeed, studies of the development of the fetal glucocorticoid system became a dominant focus of perinatal physiology for the next 40 years not only because of these effects on organ maturation, but also because of the link between the maturation of this system and the onset of parturition, particularly in ruminants. While the story in humans remains much more complex, Liggins' work on parturitional

ARTICLES

A CONTROLLED TRIAL OF ANTEPARTUM GLUCOCORTICOID TREATMENT FOR PREVENTION OF THE RESPIRATORY DISTRESS SYNDROME IN PREMATURE INFANTS

G. C. Liggins, M.B., Ph.D., F.R.C.O.G., and R. N. Howie, M.B., M.R.A.C.P.

From the Postgraduate School of Obstetrics and Gynaecology, University of Auckland, New Zealand

ABSTRAGT. A controlled trial of betamethasone Abstraction a controlled that of betamemissine therapy was carried out in 282 mothers in whom premature delivery threatened or was planned be-fore 37 weeks' gestation, in the hope of reducing the incidence of neonatal respiratory distress syn-drome by accelerating functional maturation of the field hore.

drome by accelerating functional maturation of the fetal lung. Two hundred and thirteen mothers were in spontaneous premature labor. When necessary, eth-anol or salbutamol infusions were used to delay de-livery while steroid or placebo therapy was given. Delay for at least 24 hours was achieved in 775 of the mothers. In these unplanned deliveries, early neonatal mortality was 32% in the treated group and 15.0% in the controls (p 0.01). There were no deaths with hyaline membrane disease or intra-venticular cerebral hemorrhage in infants of moth-ers who had received betamethasone for at least 24 hours before delivery. The respiratory distress syn-

R^{ECENT} experimental work showing that functional maturation of fetal animal lungs can be accelerated by stimulation of the fetal adrenal cortex or by administration of glucocorticoids suggests a possible approach to the prevention of disease resulting from pulmonary immaturity in the human. Liggins^{1,2} in 1969 noted that lambs delivered prematurely at 118 to 123 (term, 147)days after intrafetal infusions of ACTH, cortisol, or dexamethasone were viable and that, when sacrificed, their lungs remained partially expanded. This evidence of alveolar stability was unusual in view of the studies of Brumley et al.º which showed that stable pressure-volume curves and low alveolar surface tensions normally developed only after 125 days. Liggins suggested that glucocorticoids caused premature liberation of surfactant into the alveoli, perhaps by induction of an enzyme concerned

occurred less often in treated babies arouse occurred less often in treated babies (9.0%) than in controls (25.58, p. 0.003), but the difference was confined to babies of under 32 weeks gestation who had been treated for at least 24 hours before delivery (11.5% of the treated ba-bies compared with 69.6% of the control babies α 0.02).

bies compared with 69.6% of the control babies p. 0.02). There may be an increased risk of fetal death in prognancies complicated by severe hypertension-edema-proteinuria syndromes and treated with be-tamethasone, but no other hazard of steroid ther-apy was noted. We conclude that this preliminary evidence jus-tifies further trials, but that further work is needed before any new routine procedure is established. *Pediatrics*, 50:515, 1972, INSTIMASYNET, VICANONARY SUBFACTANT, CONTICOSTERION THERAPY, HYALINE MEMBRANE DISEASE. DISEASE.

with the biosynthesis of surfactant. De-Lemos et al.+ confirmed these observations by comparing the lungs of cortisol-treated fetal lambs with those of their untreated twins. They found in all animals of more than 100 days of gestation that the lungs of treated lambs had functional evidence of accelerated appearance of surfactant, Similar evidence has been obtained in fetal rabbits following injection of 92-fluoroprednisolone.6 In these animals there was also evidence of increased formation of osmiophilic bodies in type II alveolar cells and abundant osmiophilic material in the alveolar spaces of treated fetuses.^a Naeye *et al.*,⁷ in a study of 387 necropsies

on human neonates dying within 72 hours of birth, showed that the mean weight of adrenal glands was 19% lower in neonates dying with hyaline membrane disease than in those free of the disorder. In addition

(Received May 22; accepted for publication June 8, 1972.) ADDRESS FOR REPRINTS: (C.C.L.) National Women's Hospital, Claude Road, Auckland 3, New Zealand.

PEDIATRICS, Vol. 50, No. 4, October 1972

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biology was seminal to the development of an understanding of the role of the prostaglandin cascade in the onset of parturition. He demonstrated the role of prostaglandins in cervical ripening again, work which has had long-term practical translation.

However, Liggins's contributions were even broader. As a gynaecologist, he was involved in the first clinical trials of oral contraceptives in New Zealand. He was the first to suggest sequential packaging of the pill where inactive pills covered cover the withdrawal phase - an invention, he would wryly suggest that, had he known then about patents, would have made him a very wealthy man and could have forgotten about the nuisance of research grants. He found time with US colleagues to study the physiology of diving

theguardian

Premature birth

0 Save for late

Sir Graham 'Mont' Liggins obituary

Jim Thornton Monday 6 September 2010 18.41 BS1 f 🕐 🖸 🖗 🛅 🚭

Pioneer of life-saving lung treatment for premature babies



DS:

Graham "Mont" Liggins, who has died aged 84, developed a life-saving treatment for premature babies, after showing that foetal lung maturation could be speeded up by administering a steroid. This gave babies born with lungs that were not functioning properly a chance to breathe and survive. His research changed medical practice and saved hundreds of thousands of lives. d to toll the story of his far

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Mont Liggins

Graham "Mont" Liggins, investigator of the mysteries of birth and breath, died on August 24th, aged 84 Timekeeper



HE FORGOT about the sheep. He had nt to dump it in the incin from work. It was still in the car boot, and starting to smell. When he remembered, and forced it down the incinerator chute, it was already bloating, and the gassy innards instantly caught fire. The force of the explosion sent ash 200 feet into the air over Auckland.

Graham Liggins (grinning, above) was trying to find out what triggered labour. As a New Zealander, he had naturally turned to sheep. But his pursuit led to some of the most important discoveries in obstetrics, and the saving of hundreds of thousands of tiny struggling lives.

He had first not booked on the subject in the late 1940s, at the end of his clinical train

A figure of international stature, Mont Liggins' life was honoured in newspaper headlines around the world.

seals in the Antarctic, even though he had to deceive the medical examiner by providing his daughter's urine to hide the fact he had developed type 2 diabetes.

As a young perinatal researcher returning to New Zealand in 1980, I found Mont's unequivocal and generous support to be of critical importance. Indeed, he had a remarkable enthusiasm and generosity of ideas for young scientists. By then he was running his experimental flock of sheep on a park in central Auckland. He gladly welcomed me to share the flock. Monday mornings were spent doing the husbandry and Mont would palpate the sheep and pronounce with remarkable accuracy as to their gestational length and whether they carried twins or singletons. He was, however, less accurate when it came to ear-tagging them – I carry a permanent scar where he managed to tag my hand rather than the sheep! Alongside sharing the flock, we shared the fetus: he took the lungs and allowed my group to study other aspects of fetal physiology. Often I would be excited about some result only to find Mont had already done the experiment; Mont, in his classic style, only ever published a fraction of what he had done.

The deserved honours came - he was elected FRS in 1980 and knighted in 1991. Many in the perinatal community were saddened that his work, which has saved so many lives, was not recognised by the Nobel committee despite considerable lobbying. In 2001, the University of

Auckland recognised his contribution by establishing the Liggins Institute, dedicated to perinatal research.

Mont never had the ambition to grow a large group and certainly avoided university administration (and knew how to defeat – or was it to deceive? – every university accountant who came near his grants as to whether they were in funds or otherwise). Mont retired early in 1987 to avoid the challenges of university bureaucracy, but he continued in full-time research supported by his superannuation, his forestry business and his wife's clinical practice. It was more than a decade later before illnesses for both Celia and Mont caught up with them.

He was passionate about the role of the National Women's Hospital as a global centre of academic obstetrics and was devastated by the events that unfolded in the 1980s. In between, he was busy with many practical projects: his fishing, his yachting, his forestry and, most of all, supporting and enjoying his beloved family. Even when he was ill, his good humour and his interest in good science always came through. This was a man who knew how to take the most from his life, but he gave back so much more. Mont died in 2010.

Acknowledgements

This piece draws on a more extensive biography in the Biographical Memoirs of the Royal Society that acknowledges the sources for this brief tribute: http://rsbm.royalsocietypublishing. org/content/roybiogmem/early/2013/03/28/ rsbm.2012.0039.full.pdf

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Two revolutions in one lifetime: HPV



Dr Michelle Harris FRANZCOG

In 1990, in New Zealand, and 1991, in Australia, the introduction of a National Cervical Screening program revolutionised our specialty: the incidence and mortality of invasive cervical cancer were dramatically halved in only ten years.¹ The lives of up to 300 Australian and New Zealand women per year were saved, and more were spared the potential morbidity associated with treatment of invasive cervical cancer. On a worldwide scale, cervical cancer is the fourth-most common cancer in women and the second-most common cause of cancer-related death.² There are more than 500 000 new cases and approximately 266 000 deaths from cervical cancer each year. The greatest disease burden is in less-developed regions of the world, where more than 80 per cent of cervical cancer occurs. The cost and infrastructure required for a comprehensive screening program is prohibitive in many of these countries.

We are now watching a new revolution: the introduction of the human papillomavirus (HPV) vaccine to the national immunisation schedule is expected to decrease the incidence of invasive cervical cancer further, while simultaneously having an impact on the incidence of high-grade cervical dysplasia, treatment-related sequelae, the incidence of other anogenital cancers, and the suffering associated with genital warts. It is anticipated that prophylactic HPV vaccines for types 16 and 18 administered to young women before the onset of sexual activity can prevent 70 per cent of cervical cancer cases. There is hope that this strategy will become accessible to populations where screening has not been possible, so that the worldwide incidence of cervical cancer will also fall.

Harald zur Hausen's pioneering research in the early 1980s isolated HPV-16 DNA from 50 per cent and HPV-18 DNA from 20 per cent of cervical cancers.³ HPV DNA was similarly isolated from precursor cervical lesions. A causal link in the development of cervical cancer was hypothesised, and confirmed by further research. In 2008, zur Hausen was awarded the Nobel Prize in Medicine for his role in these discoveries that greatly increased our understanding of HPV-mediated carcinogenesis and provided the foundation for the innovation of prophylactic vaccines for cervical cancer.

Cervical cancer was the first cancer acknowledged as virtually 100 per cent attributable to an infection.⁴ Until recently, neither treatment techniques nor screening strategies, to any extent, utilised this knowledge.⁵ However, following on from zur Hausen's crucial studies, research groups all over the world recognised that a vaccine that induced neutralising antibodies to specific 'high-risk' HPV genotypes could theoretically prevent cervical cancer. The challenge was to create a vaccine against a virus that provokes a relatively subdued immunological response naturally and throws up additional obstacles such as using the differentiation of epithelium to regulate its lifecycle, preventing traditional approaches to the production of virus for vaccine in vitro.⁵

Jian Zhou and Ian Frazer's 1991 breakthrough was to use recombinant DNA technology to create virus-like particles (VLPs) of the recombinant HPV-16 L1 capsid protein that mimic the papillomavirus structurally and elicit high titres of neutralising antibodies.⁶ After filing a patent application, Zhou and Frazer licensed their technology in 1995 to a pharmaceutical company to develop a prophylactic vaccine against HPV 16, 18, 6, 11. Within three years of development and testing, the first human trials successfully took place in 1998. In 2002, the first randomised placebocontrolled trial of the efficacy of a VLPbased HPV vaccine showed 100 per cent efficacy in preventing persistent HPV infection in young, previously uninfected women.⁷ Further randomised, doubleblind, placebo-controlled trials of both the bivalent and quadrivalent prophylactic HPV vaccines followed.^{8,9} Efficacy rates in preventing persistent HPV infection and associated clinical lesions were found to be extremely impressive; the vaccines were found to be safe and well-tolerated. Costeffectiveness and health economic impact studies were of additional importance to the growing literature.

By mid-2006 the quadrivalent vaccine (Gardasil) was registered by Australia's Therapeutic Goods Administration (TGA) and the bivalent vaccine (Cervarix) was registered in 2007. Australia was the first country in the world to introduce a government-funded universal HPV vaccination program in 2007. The initial cohort was 12–13-year-old girls, alongside a two-year catch-up program for women up to 26 years old. In 2013, 12–13-yearold boys were added to the program. New Zealand commenced a national vaccination program in 2008.

The vaccines were developed to target the two HPV genotypes that zur Hausen and international epidemiological studies^{10,11} had identified as causing approximately 70 per cent of cervical cancer – HPV-16 and 18. The prophylactic vaccines were actually registered by the TGA prior to the completion of extensive local epidemiological studies. However, a meta-analysis of 533 Australian cases of cervical cancers typed for HPV was published in 2008¹² and reported HPV-16 was present in 60.4 per cent, HPV-18 in 19.7 per cent and HPV-45 in 4.6 per cent of histologically confirmed cancers. Taking into account that 13 cancers had both HPV-16 and 18, the author surmised that the vaccine could have prevented 77.7 per cent of cervical cancers in Australian women. The same meta-analysis looked at a subset of 83 adenocarcinomas – typing demonstrated HPV-16 in 28 per cent, HPV-18 in 41 per cent, and HPV-45 in ten per cent. These regional data were consistent with the previously reported international data.

'...we have entered a new era, where improved understanding of the pathogenesis of cervical cancer...allows us to tackle cervical cancer more cleverly.'

Given the 10–20 year latency between HPV infection and the development of cervical cancer, it will take time to demonstrate a reduction in cancer incidence owing to HPV vaccination, particularly as the early adopters have been countries with an already low incidence of invasive cervical cancer. Even now though, less than ten years after vaccination started, we have reason to be excited by the impact of the HPV vaccine on our practice. A 2011 study of first-time STI clinic attendees shows a 59 per cent drop in genital warts in vaccineeligible women.¹³ The Australian Institute of Health and Welfare reports a 63 per cent drop in high-grade abnormalities by histology in women aged less than 20 years from 2007 to 2013.¹⁴ A less marked decrease is reported in women aged 20-24 years during the same period, while an increase is seen in all other screened age groups. Extrapolating from these statistics, significantly fewer young women have experienced the psychological distress associated with diagnosis and treatment of high-grade cervical lesions, as well as potential treatment-related sequelae, than in the decades before immunisation.

As with all new vaccines, a strategy for reporting adverse effects from the two prophylactic HPV vaccines has been in place since their introduction. This information, coupled with the initial safety studies, has shown that the vaccines are well-tolerated, with no increased risk of serious adverse events when compared with placebo. Local injection site discomfort, erythema and swelling are the commonest side effects. The occurrence of headache, fatigue, fever and myalgia are similar to occurrence with placebo, as is the rate of syncope. The incidence of anaphylaxis is approximately 2.6 cases per million doses, which is similar to other vaccines.

Research into the duration of the prophylactic effect of the bivalent and quadrivalent vaccines is ongoing, but seems to be sustained for at least ten vears. Alternative dosing regimens have been investigated and the World Health Organization (WHO) recently changed its recommendation to a two-dose regimen for females under 15 years (0 and 6 months) based on non-inferiority studies, for reasons of cost-saving, programmatic advantages and to aid vaccine uptake.¹⁵ A third vaccine has recently been approved in the USA – a nonavalent HPV vaccine (Gardasil 9) protects against an additional five HPV types (HPV-31, 33, 45, 52, 58) and could potentially prevent up to 90 per cent of cervical cancer.

Population-based cytological cervical screening has been a powerful tool in the reduction of cervical cancer rates, but we have entered a new era, where improved understanding of the pathogenesis of cervical cancer – coupled with the research and innovation of Zhou and Frazer's VLP technology – allows us to tackle cervical cancer more cleverly. Primary prevention with the HPV vaccines has the potential to decrease cervical cancer incidence not just in developed countries, but also on a worldwide scale. Although the principal target is cervical cancer, there will be an additional benefit of reduction of other HPV-related cancers (vulvar, vaginal, anal, oropharyngeal), genital warts and highgrade pre-invasive lesions. The stage is now set for a more refined HPV-based screening strategy that acknowledges the aetiology of cervical cancer and integrates synergistically with the preventative strategy.

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RU486: behind the headlines



Prof Caroline de Costa AM PhD, FRANZCOG James Cook University School of Medicine

Howard. Harradine agreed to support the government's bill for the partial privatisation of Telstra in return for Howard's amending legislation governing the Therapeutic Goods Administration (TGA), to prohibit the import, manufacture or use of the drug RU486 (mifepristone) in Australia without the special permission of the Federal Minister for Health. The 'Harradine Amendment' effectively made mifepristone for medical termination of pregnancy (MTOP) unavailable to Australian women.

For some years, there was muted opposition to the Amendment from the medical profession, most notably the late David

Healy; politicians from all parties, but particularly the Democrats' Lyn Allison; and pro-choice groups. However, it began to gather force in 2005. Meanwhile, in Cairns, we had become aware from Dr Adrienne Fleming of a possible loophole in the TGA legislation that might enable us to import the drug for use in private practice for the purpose of MTOP. This was the Authorised Prescriber (AP) legislation that exists to allow medical practitioners to import and use drugs registered and available overseas, but not in Australia, for serious medical conditions. We set about completing the volumes of paperwork required for AP approval from the TGA, while feeling, because of the Harradine Amendment, it was unlikely that we would gain such approval, particularly as the Minister for Health at the time was Tony Abbott, an outspoken opponent of abortion.

In October 2005, one of us (Caroline de Costa) published in the *Medical Journal of Australia* an article reviewing overseas use of mifepristone for MTOP and calling on the government to make the drug available to Australian women. Immediately, a number of politicians mostly, but not exclusively, women and from across all parties, made contact with us and there were invitations to Canberra to discuss ways to overturn the Amendment and then subsequently gain access to mifepristone in Australia. Many individual doctors and doctors' groups,



The first dose of mifepristone to be legally imported into Australia.



Dr Michael Carrette FRANZCOG Senior Lecturer James Cook University School of Medicine

In 1996, Brian Harradine was an independent Senator representing Tasmania and he held the balance of power during the first Howard government, which often needed his vote in the Upper House. That year Harradine, a staunch opponent of abortion, made a deal with including RANZCOG, the Federal AMA and rural medicine groups, and many pro-choice groups, including Children by Choice, Reproductive Choice Australia, state Family Planning associations and others, came together in a spontaneous, but well-organised, effort to change the legislation. Get-Up also became involved in the campaign. Very quickly there was huge media interest in the whole question of medical abortion, most of it supportive of the need for change. There was also concerted opposition from anti-choice and 'right to life' groups. But the strong message from the proponents of change was: let the TGA decide – not the Minister for Health.

The climax of this feverish activity came in February 2006 when four Senators – Lyn Allison (Democrat), Claire Moore (ALP), Judith Troeth (Liberal) and Fiona Nash (National) – brought a private members' bill to the Senate that was passed. That bill went a week later to the House of Representatives where it was subject to a conscience vote and also passed; the Harradine amendment was consigned to the dustbin of history.

However, the rescinding of the Amendment did not mean that the drug immediately went on sale in pharmacies across the country. In fact, no major drug company or distributor was willing to import or manufacture mifepristone in Australia. However, in Canberra, our application for AP approval for mifepristone had been quietly making its way through the echelons of the TGA and, in April 2006, we received permission to import and use the drug in Cairns. We had already established contact with colleagues in New Zealand, who had been performing MTOP since 2001, and in May 2006 we received our first batch.

We had no clinic in which to perform MTOPs so, after appropriate discussion with women requesting abortion, we administered the drug in consulting rooms in Cairns and sent the women home in the care of a support person. Aware of the media spotlight on us, we were extremely cautious in choosing patients: we gave women our mobile phone numbers and kept in contact meticulously. Soon, however, we realised what all the overseas studies had shown: mifepristone plus misoprostol used in appropriate women in the early weeks of pregnancy is a safe method of termination of pregnancy very acceptable to women themselves.

We wrote to a large number of our gynaecological colleagues urging them to make similar applications – Jan Dickinson from Perth, Chris Bayly from Melbourne and Terry McGee from Sydney were the first to do so, but for the first three years numbers were small. Then doctors from South Australia and the Marie Stopes (MS) organisation also gained AP approval, and numbers of MTOPs in Australia increased rapidly. In 2012, the drug got full TGA approval for distribution by MS Health and in 2013 PBS listing. From 2009 onwards, the Sexual Health Clinic in Cairns Hospital, under Dr Darren Russell, also provided MTOP, which gave strong support for our efforts.

What was it like for us in those early years? We certainly received much media attention, almost all of it well-informed and wellpresented. We received a considerable amount of (anonymous) hate mail that, as advised by Cairns police, we placed in a special file, handling it as little as possible to conserve the writers' fingerprints! However, for every piece of negative mail there were ten messages of support. At one stage there was a stalker, eggs were thrown and trees ring-barked on our personal properties and police protection was provided. The stalker told the Cairns Post that he intended to 'run us out of town'. This brought a huge outpouring of support for us in the Post from our fellow citizens and the stalker moved on to other targets.

In August 2005, we sat on the veranda of Mike's house in Cairns and wondered if we were mad to make the TGA application – surely it would never be approved! By August 2006, the Amendment had been overturned and we were providing mifepristone to Cairns women. This was thanks to the efforts of thousands of people right across Australia. We were pleased and proud to have been part of this movement.

VIEWPOINT

VIEWPOINT

Medical abortion for Australian women: it's time

equine M De Costa

econog, a yeang woman from a royal community presented to doctor in a small country hospital some distance from her homrequesting termination of programs;. She was the mather of tw m aged under 3 years, both delivered before 32 weeks gestation

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At 26 weeks of programs, she presented again to the convery hospital, severely 10 with pre-champia. Me was transformed by an to the town on which the night have had the programs, terminant, where the underware mergency concernor section in a public loopital. The right dependency unit. The cost of ker transfer and hospitalisation was covered from the public parts.

This woman's story could have been very different if Australawomen, like how in ab United Stars, Canada, the Unito-Kingdom, mach of Weistern Europe, Rossa, Chana, Israel, Nee Deen very different Fastorge, Rossa, Chana, Israel, Nee heat access to medical abortion. This woman's story could have been very different If Australian women had access to millepriston (formerly known as 812-480), ad rug which is safe, effective, chan or produce, and now widely used overses for medical abortion. More than 1.5 million early thefore 9 weeks terminations pergramely have been performed in Europe, and around 400,000 the US, using milepristors together with prosaglandin analogue here is a large body of Instrutor now available on the administr non, effectiveness, side effects and risks of the medication, as we much information about its accentaling to severa¹¹.¹¹

Identistone is a configure densit the bit

progeneous it was deviced that blocks the actions of progeneous it was deviced in France in 1980 and underwent clinical trails in France and Switzerland in 1981.¹³¹² It was been for use in France in 1988, the UK in 1991, and the US in 2000. The drug can be used for emergency contraction.

- ABSTRACT • Medical termination of pregnancy with millepristone, a progesterone antagonist, is available to worten in No America, the United Kingdom, much of Western Euro
- roustial, chima, strant, New Zealand, Turkky and Turkita, but not Australia. • Expensions of indepristone use in around two million abortions has shown that it is safe, effective, chesp to
- produce, and highly acceptable to women. Melepristone is usually used in combination with a
- provagiance analogue, such as misoprosticl, these drugs have been added to the World Health Organization's list of essential medicines for developing countries.
- many of the inequities of access to abortion, and is critical for many women in rural areas and women in some ethnic groups whose access to surgical abortion is limited

MJA 2005; 183 378-380

separation of the developing embryo and placenta from the trine will; it also causes cervical softening and the release of degenous protaglandins. When used for medical termination of egatarcy, mileprotone is usually administered with a prostaglanin analogue (either misoprosol or geneprosol, which brings out exeptision of the uterine contents.

In early programs, various drug regimens have been used, most momenly micprintions (200 mg only) followed by the prostagandm analogue misoprotol fone or more dows vaginally or early), either connecting at the time milliprintene is given or 1days hare. Misoprotol muy be given by a clinican or adminited by the woman hereft¹⁻³⁵ (Misoprotot) is currently availble in Australia and, although not listed for gynaecological distantent, it is used for cervical diffusione bofes supplical userane excession and for poorpartum hatemorthage; it has also heren used retrast for test interogriptic apportances alboritom 1.

In 93%-98% of cases, administration of the drug combination leads to complete abortion. In the remainder, the abortion needs to be completed by aspiration of uterine contents by an appropriately qualified doctor. In a very small number of assume, have senter are easily programs, y commution that the programs y is intranset get essential, and any singgestion of estropic programs process gates specifical and any singgestion of estropic programs process generations are appreciated and the specific process of the specific programs of the specific process of the specific scattering of the specific process of the specific program for the works in order of the specific process of appropriate and specific process of the specific process of the specific process of the specific process of the specific generation of the specific process of the specific programs the offered (pain and because the specific product) and process and the works should be specific product of the process) and the works should be specified and the works should be defined offered on the specific product of the products of properties have been removed a specific and the works the product of the offered ontractic product works by the specific product of the offered ontractic product works and the works the specific defined of the specific product of the specific product of the offered ontractic product works and the works the specific defined of the specific product of the specific product of the offered ontractic product works and the works the specific product of the offered ontractic product of the specific product of the specific product of the offered ontractic product of the specific product of the specific product of the offered ontractic product of the specific product of t

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Mifepristone in Austra

It is clear from this summary that reached accretion could be quickly incorporated into the practice of existing vortalian abortion services, and could also easily become part of the practice of those gyraecologiets, general practicitieners and family planning doctors who wished to provide it in particular in could become a trail and accessible ontoine for some in trail afree.

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In 1990, the Interintional Federation of Ohierrico and Gynacolog (FIGO) student bin "after appropriate concellengt, a sweman as the right to have access to medical or surgral induced bettom, and. — Buildness service have an obligators to provide useh services as safely as possible." This view was supported by the World Heidel Origination which, in 2003, publiced Sydaleritors todonial and piloty guadesec to assis health care providents on make surgeal and medical abertion eads and accessible." More accessibly WID has added mileprotose and mosportal to its list of escently WID has added mileprotose and mosportal to its list of escently WID has added mileprotose and mosportal to its list of escently WID has added mileprotose and mosportal to its list of escently MID has added mileprotose and mosportal to its list of escently MID has added mileprotose and mosportal to its list of escently MID has added mileprotose and mosportal to the list of escently MID has added mileprotose and mosportal to the list of escently MID has added mileprotose and mosportal to the list of the American Gollage of Obsertments and Gyncologia there been outspoken in their support for the introducion of motical abortion in their respective domains and health care prediscional babits are need for women.^{13,16} In Australia to date, there have been distribution who and an added health care prediscional babits are protocol and an added health care protocol babits.

It as a ratche in the Journal in 2004, de Creignij and Swielecis comined the discipances in aboutton laws between Austalan tates, and appred the case for uniform determinidisation of ensuing laws.²⁴ In addition, they pointed out that, ablough abouton is legal in some sumations in all state, there are marked largely overcome by the introduction of medical aboution in this country.

The topic of abortion is an emotive and controversial one recent media debate seems to have died down, and no doubt

The opinion piece that started the ball rolling.

Celebrating more than 50 years of the Pill



Dame Margaret Sparrow DCNZM, MBE, BSc, MBChB, DipVen, FAChSHM, HonDSc, FRANZCOG(Hon)

The idea of taking something orally to prevent pregnancy was not new. Throughout history and in many cultures, women have swallowed potions in an effort to control their fertility. However, the scientific understanding of reproduction brought exciting new possibilities. By the 1930s, scientists knew that progesterone inhibited ovulation in animals, but it took another three decades and some fortuitous events before 'the Pill', as it is popularly referred to, became a reality. This account pays tribute to the key contributors to that development.

Russell Marker (1902–1995)

In 1940, progesterone was one of the rarest and most expensive drugs in the world, selling for \$200 a gram. It was extracted from animal sources and was in great demand for the treatment of women with recurrent miscarriage. Prof Marker, a chemist at Pennsylvania State University, believed he could find a better source in plants. In the summer of 1940, he tramped alone through the wilds of Mexico and discovered a source in the lumpy root of a wild Mexican yam. No one would finance his project so he left the university and established a laboratory in a shed in Mexico City. Working independently, he developed the first mass supply of progesterone and thus became rich. For a few years he was involved in the pharmaceutical production of progesterone at Syntex Laboratories, but in 1949, aged 47, he retired and never returned to science.

Dr Carl Djerassi (1923–2015)

Progesterone was most effective when administered by injection. An orally active form was needed and Djerassi was responsible for this breakthrough. He was born in Vienna, Austria, and raised in Bulgaria. His parents were doctors and, when he was 16, he and his mother immigrated to the USA. When Marker left Syntex Laboratories, Djerassi, then a young chemistry graduate, was appointed to lead the firm's steroid research. In 1951, his team produced the first orally active progestogen called norethisterone, still used in formulations today, such as Noriday and Brevinor. Djerassi was not only a distinguished chemist, but also a poet, novelist and playwright.

Margaret Sanger (1879–1966)

Margaret Sanger was the prime motivator in the development of the Pill. The sixth of 11 children, after nursing her mother who had tuberculosis, she trained as a nurse. In New York she saw the effect of too-frequent childbearing on the health of women and children and the tragedy of unsafe abortion. She became an ardent proponent of birth control, a term she promoted. In 1914 she challenged the repressive Comstock laws, which forbade distributing contraceptive information, by releasing material expounding the benefits of douches, condoms and pessaries. To avoid prosecution she fled to Europe and eventually the case against her was dismissed.

Back in the USA, in 1915, she advocated use of the diaphragm, which had to be smuggled into the country from Europe. In 1916, she established the first US birth control clinic in Brooklyn, New York, and for this daring venture she was convicted and served 30 days in jail. After her release she won an appeal, opening the way for physicians to give birth control advice. She published a monthly magazine Birth Control Review and in 1921 founded the American Birth Control League, the forerunner of Planned Parenthood. In 1927 she organised the first World Population Conference in Geneva. At a meeting in India, in 1952, she was one of the founders of the International Planned Parenthood Federation (IPPF).

She married twice, first to Bill Sanger, the father of her three children, and then to an older millionaire, Noah Slee, who helped finance her projects. In December 1950, at the age of 71, she was introduced to Dr Gregory Pincus at a dinner party and a spark was ignited when she found he was interested in reproductive hormones. She implored him to find a better method of contraception for women and secured a small grant from Planned Parenthood that enabled him to commence research on this project.

Katharine McCormick (1875–1967)

Sanger told her friend Katharine McCormick about Pincus's research. In 1953, frustrated by Planned Parenthood's meagre interest and support, the two women met with Pincus and, with McCormick providing a 50-fold increase in funding, encouraged him to dramatically expand the scope of the research. McCormick came from a privileged background. Her father supported education for women and she was the first woman to graduate as a biologist from the Massachusetts Institute of Technology. After graduation she married Stanley McCormick, but two years later he was diagnosed with schizophrenia and then dementia, requiring full-time care. She chose not to have children for fear of passing on the illness. She met Margaret Sanger in 1917 and was a keen supporter of birth control, a feminist, suffragist and philanthropic supporter of education for women as well as schizophrenia research. Her husband died in 1947 and she inherited his wealth, largely generated from the McCormick firm, International Harvester. Now over 70, she was free to pursue her own, rather than the McCormick family, interests and she provided almost the entire \$2 million for the development of the Pill.

Dr Gregory Pincus (1903–1967)

Pincus was born in New Jersey into a Jewish



Friends Margaret Sanger (left) and Katharine McCormick (right) joined forces to fund the research that led to the contraceptive pill.

family. He attended Cornell and Harvard Universities, then Cambridge University, in the UK, and the Kaiser Wilhelm Institute for Biology in Berlin. He returned to the USA to pursue his career as a biologist and reproductive physiologist, but because of controversial research on in vitro fertilisation he lost his position at Harvard and henceforth worked outside academia. With the grant provided by Planned Parenthood he confirmed earlier research on progesterone and then asked pharmaceutical companies to supply chemical compounds with progestogenic activity. Nearly 200 compounds were screened by his team; the three most promising were Syntex's norethisterone (1951) and Searle's norethynodrel (1952) and norethandrolone (1953). However, since Pincus was not a clinician he needed a collaborator in order to prove the safety of the Pill in human trials.

Dr John Rock (1890-1984)

Rock was clinical professor of gynaecology at Harvard. His specialty was infertility. At a scientific conference in 1952, Pincus and Rock discovered they were using similar approaches to achieve opposite goals. Rock was using hormones to stop ovulation for a three-month period to see if the ovaries would rebound after a rest period. About 15 per cent of women became pregnant following this treatment. In 1954, at Pincus's suggestion, he initiated the first trials on infertility patients using the three different progestogens. Trials of the Pill as a contraceptive could not be performed in Massachusetts because dispensing contraception was still a felony in that state.

Rock found Searle's norethynodrel gave better cycle control and selected this for the first contraceptive trials in women. Serendipitously, it was discovered that the drug was in fact contaminated with a small amount of oestrogen and this was the origin of the combined pill containing oestrogen as well as a progestogen. This combination gave better cycle control than progestogen alone. The first large-scale contraceptive trial in women began in April 1956, supervised by Dr Edris Rice-Wray (1904–90) in the Caribbean Island of Puerto Rico, a selfgoverning territory of the USA.

On 10 June 1957 the FDA approved Enovid, a combination of norethynodrel and mestranol, for menstrual disorders and, on 9 June 1960, for contraceptive use. Searle did not market Enovid commercially as a contraceptive until July 1961 and it was never introduced into New Zealand. The first pill in New Zealand was Schering's Anovlar, introduced in 1961.

Rock was a Catholic and a father of five.

At the age of 70, he launched a one-man campaign to gain Vatican approval of the Pill, arguing that the church should consider it a natural form of birth control. In 1963 he published The Time Has Come: A Catholic Doctor's Proposals to End the Battle over Birth Control. It was a crushing defeat, in July 1968, when the Pope officially banned the Pill in the encyclical *Humanae Vitae*. When Rock died, at the age of 94, he was still bitterly disappointed the church refused to change its stance on the Pill.

It is a remarkable story; an eccentric chemist driven to find a plant source of progesterone; another who synthesised a progestogen that could be swallowed; two elderly women with a life-long passion to improve the lot of women and with the money to finance their vision; a maverick reproductive scientist who accepted their challenge and a Catholic doctor whose work linked infertility with the control of fertility. They would all be astounded at the influence that their endeavours have had on the lives of women. Reliable contraception has enabled women to think of roles beyond that of wife and mother and for couples to enjoy sexual expression without the fear of an unintended pregnancy.

Further reading

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Victoria's secret: chloroform and the acceptability of analgesia for birth

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Among the crimes of Agnes Sampson, a midwife and the first woman to be burned at the stake for witchcraft in Scotland, in 1591, was that she had used her supernatural skills to relieve the pain of labour. The dominant (in other words, male) view throughout Europe was that such interventions were potentially dangerous pain was physiologically important for the normal progress of labour and to prepare the fetus for birth. More importantly, pain relief in labour was sinful. God had decreed that women should bear children in pain as punishment for Eve's surrender to temptation; how dare anyone presume to interfere with His will?

These attitudes were of little practical importance for most of human history. Apart from opium, which had been used for pain relief for hundreds of years, there were few effective treatments. Moreover, until the 16th century, opium could only be administered effectively by smoking. It was the Renaissance physician and alchemist, Paracelsus, who recognised that opium was soluble in alcohol, resulting in an orally effective form, which became known as laudanum, a mainstay of classical medicine. It was not until 1885 that Alexander Wood described the use of the hypodermic needle and syringe to further enhance the usefulness of opium alkaloids. However, the mid-19th century also saw the discovery of two other potent forms of pain relief, diethyl ether and chloroform. Chloroform initially gained popularity in Europe as a 'party drug' and it was only after the Scottish obstetrician James Young Simpson and a group of his friends had been rendered unconscious in that context that Simpson recognised its potential for use in his patients. He is credited with giving the first general anaesthetic for childbirth, in 1847, and soon became a strident advocate.

The popularity of chloroform-assisted childbirth grew rapidly, despite the usual quasi-medical and religious objections, mainly as a result of the demand by women. The reported use of chloroform by prominent women helped the cause. One of the most notable was Emma Darwin, who was administered the drug by her famous husband, Charles, and who went on to demand chloroform for subsequent births.

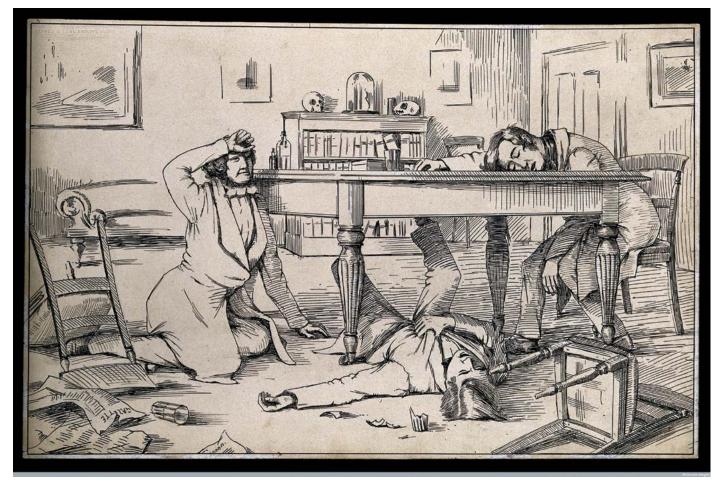
Undoubtedly, the ultimate endorsement should have come from Queen Victoria herself, and so it is often stated, but it was not to be. Despite ultimately giving birth to nine children, it was well-known that the Queen disliked pregnancy, describing it as 'wretched'. She had also suffered mild postpartum depression after her first two pregnancies. It was therefore not surprising that, after receiving a pamphlet from the Duchess of Sutherland during her sixth pregnancy, both the Queen and Prince Albert developed a keen interest in the potential of chloroform. Unfortunately, the first death from chloroform, in a 15-year-old girl, had recently been reported (chloroform was ultimately abandoned owing to its tendency to cause dangerous cardiac arrhythmias) and the royal physicians expressed their strong opposition. However, by Victoria's eighth pregnancy, in 1853 (with Prince Leopold), confidence in its use had grown. Prince Albert, a long-standing champion of the sciences, had become an advocate and had discussed the subject with London's foremost exponent of chloroform, the brilliant Dr John Snow, who would, the following year, cement his place in medical history when he correctly identified the Broad Street pump as the source of London's cholera epidemic.

So it was, that on 7 April 1853, Dr Snow was summoned to administer chloroform to the labouring monarch. Dr Snow's notes recorded '...her Majesty expressed great relief from the application, the pains being trifling during the uterine contractions...'

Surprisingly, in the medical bulletins immediately following the birth and in the newspapers, no mention was made of the use of anaesthesia. A report was eventually published in an editorial in the *Association Medical Journal*, the forerunner of the *BMJ*. It has been suggested that the information in the editorial came from the vocal and ardent James Simpson, who obtained it



John Snow originally described his inhaler in 1847. One canister was used for cold water and the other for chloroform. The brass face mask was attached to the end of the flexible tube so the patient could inhale the anaesthetic vapours. (Science Museum, London, Wellcome Images reproduced under licence CC BY 4.0.)



The effects of chloroform on Simpson and his friends (pen and ink 1840s). (Wellcome Library, London, reproduced under licence CC BY 4.0.)

from the royal obstetrician, Sir James Clark. The *Lancet* treated the information as mere rumour, advising that 'the Queen was not rendered insensible by chloroform or any other anaesthetic agent'. This was true as far as it went – Snow had administered chloroform on a handkerchief and successfully maintained light sedation only.

None of the British lay newspapers made much of these reports, though a couple did reproduce the facts, without comment. These included the *London Globe*, but neither the *Times* nor the *Morning Chronicle*, London's biggest papers, picked up the story. Indeed, it was not until 1869, in John Snow's obituary, that the *Times* alluded to the fact at all.

Although there was a gradual increase in the use of chloroform during labour in the ten years or so following Queen Victoria's experience, the real push for routine pain relief during labour had to await the 'first wave' of feminism early in the 20th century. Early feminists supported the relief of pain during labour as a liberating influence, allowing women choice and control. They linked the availability of effective analgesia with improved maternity care in general. They demanded that childbirth be taken more seriously, including the 'right' to bear children in hospital, where responsive, respectful medical care could be expected.

So why did the revolutionary use of chloroform during childbirth by Queen Victoria pass with barely a whimper? Was there some kind of conspiracy to keep it secret? There is no evidence of an overt conspiracy, but it is clear that both the medical and religious establishments retained their disapproval of 'interference' in the natural and sacred process of labour. Though one could not openly disapprove of the choices made by the Queen, it seems to have been tacitly understood that such activities should not be promoted to the masses.

By the time the early feminists came on the scene around 1900, chloroform was already on the wane and the feminist campaign for pain relief in labour ultimately coalesced around a technique, subsequently also discredited and abandoned, called 'twilight sleep', which involved the use of morphine and scopolamine (hyoscine) in combination. Despite improving technologies, such as epidural analgesia, the second wave of the feminist movement, in the 1960s, held views diametrically opposed to those of their predecessors and rejected pain relief as part of the male medicalisation of childbirth in favour of 'natural birth'. They drew support from other pseudo-scientific promoters of natural childbirth, such as Lamaze and Dick-Read. For the second-wave zealots, a woman who 'gave in' to pain relief had fallen under the spell of the male doctors and was considered something of a turncoat.

Fortunately for women everywhere, there is now a growing third wave among academic feminists, which again favours the use of pain relief as a valid feminist choice for the labouring woman. Queen Victoria may yet be vindicated!

Further reading

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Caesarean section in the news: plus ça change...

A/Prof Paul Howat FRANZCOG Clinical Program Director, Women's and Children's Services Northern Health, Victoria Clinical Associate Professor **University of Melbourne**

It is 1893, and the fact of a caesarean section operation performed in New York is considered remarkable enough to be reported in the New York Times. Even more remarkable, and the chief point made in the article, is that both mother and baby survived.

Fast forward 123 years and much has changed. Caesarean section is commonplace, unremarkable and, on the whole, safe for mother and baby. Progression and development of anaesthetic and surgical techniques, antibiotic usage and a better understanding of the physiology of labour and the intrauterine environment have resulted in this being a safe operation. A shorter time limit on length of

The Cusarean Operation.

The Cusarean operation was performed at the New York Post Graduate Medical School and Hospitul yesterday for the first time in the history of that institution. This is a dancerous

Initiony of that institution. This is a dancerous and a rare operation, and it is never resorted to inless the birth of a abild cannot be elucited by natural means. During the last year there were only sight recorded operations of this kind in the United States. How many of these were successful there are no available statistics to show, but it is rare that both mother and abild survive. It is no operation which has been performed only in desperate chase, although the recent advances the danger. Youtorday's operation was entirely encess-

Yesterday's operation was entirely encess-ful, in that both mother and child survived.

The New Hork Times

Published: February 8, 1893 Copyright © The New York Times labour, a reduction in high assisted vaginal birth procedures, the widespread use of electronic fetal monitoring and other factors have resulted in the operation increasing in frequency to the point where roughly one-third of all births in Australia are by the abdominal route.

There is no doubt that caesarean sections save lives, but this is hard to quantify in the developed-world setting where perinatal death is rare and maternal death is almost unheard

of. Headlines today are more likely to report concern about ever-increasing caesarean section rates, or 'botched' and 'bungled' deliveries where a caesarean section was either not performed or performed too late. Therein lies the tension for the modern obstetrician – damned if you do too many, and damned if you don't do enough. Litigation and defensive obstetric practices contribute to this predicament, as does patient choice. The operation of caesarean section has become so safe that many women consider it reasonable to request it is performed on the basis of maternal choice. There are few other operations, apart those within the realm of plastic surgery, where a request for surgery is commonly made for non-medical reasons. As a departmental director in a public hospital, I am responsible for managing limited resources in a growing service. As such, if a woman cannot articulate a medical reason for requesting an elective caesarean section, it has been my position to decline any requests for non-medical caesarean section.

This year, I reflect on the fact that I have now been an obstetrician for 20 years. This has been completely in the sphere of public obstetrics, so I make no comment or observations on private obstetric practices. Over this time caesarean section rates have continued to rise, litigation payouts are measured in the tens of millions, and even the operation itself is becoming more

Natural births out as push gets the shove



Ever since 1893, with reports of the first successful operation, caesarean section has rarely been out of the news.

difficult under certain circumstances. I will discuss some of these experiences, not to draw any conclusions, but to try and link what I have observed and experienced to the issues I think are important today.

Firstly, death is still with us. I have had the misfortune to have a patient die on the table from a major placenta praevia percreta at 24 weeks; a young woman who exsanguinated in a regional centre before transfer could occur. This remains the worst clinical experience of my life, I did everything I could, but blamed myself for her death for months afterwards, and I still have terrible memories of her family screaming at me that I had killed their mother and sister. In much of Australia, where women may only have one or two caesarean sections, placenta percreta is extremely rare, but this is not the case is some demographics or for women who want large families. Caesarean section can save lives, but it can also take them.

Death is also just across the international border. When I worked in Cairns, we had a number of women who came to us from Papua New Guinea with neglected, obstructed labour of several days duration with a dead fetus and on death's door themselves. The absence of fairly simple facilities and training in this developing country on our doorstep mean that women and their babies die on a daily basis, and caesarean sections could save lives. I wonder, for the

handful of desperate women who have the resources to be carried by their relatives, travel down rivers in a cance, then journey across the Torres Strait by outboard motor to Australia, how many other women have died? In Australia we've successfully quarantined thoughts of death related to birth, but in many countries new life and death are inextricably linked.

Moving away from death to the mundane, my experience as a public hospital specialist has made me consider other aspects of caesarean section. Hospital administrators and health departments are critical about caesarean section rates and, in leadership roles, I have often been asked to 'please explain'. At the same time, there can also be punitive responses for the failure to perform a timely caesarean section. Vaginal birth after caesarean section is encouraged and rates measured, and if your hospital is an outlier you are criticised. But VBAC carries its own risks, and it comes down to patient choice. At times I have felt almost forced into encouraging women into having a VBAC, when I truly believe that counselling about these choices should be evidence based, non-directional and the decision ultimately up to the patient. Obesity is a major issue, and performing an emergency caesarean section on a morbidly obese woman is unpleasant and high risk. It is not an easy decision. In the desire to keep caesarean section rates down, do we push women too long and too hard in labour? Do we

lose situational awareness and fail to recognise or justify away deteriorating fetal condition because we are afraid of being criticised for performing an 'unnecessary' caesarean section. I think this has happened to all of us. Difficult second-stage caesarean sections risk injury to the mother and baby, and also the surgeon. There have been fetal deaths from inability to deliver the fetal head, and fractured skulls from excessive efforts to do so. I have a number of colleagues who have acutely injured their wrists, arms and shoulders performing difficult caesarean sections. One was off work for six months after a fractured wrist, which required surgery. The miracle of safe caesarean section is in danger of becoming an unenjoyable burden.

My final comment is that as well as a full explanation before a procedure such as caesarean section, debriefing afterwards is important too. A woman may feel upset, concerned, angry, cheated out of a vaginal birth, or be worried about an issue or aspect that has not occurred to us as the caregiver. Listening to and debriefing a woman and her family after an emergency birth, even for something you may regard as routine, is vital. After a bad outcome, this should be extended to the staff as well. If this had been offered to me after my appalling experience above, it may have helped me deal better with what happened and its aftermath. Instead, I managed with the unofficial support of my close colleagues and family, but the experience taught me a lot about not only my own reactions and resilience, but also how to help others after a distressing event.

Caesarean section is common, routine and safe most of the time. Complexities and consequences still abound; it is still major surgery and should be respected as such.



Liam Croy

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West Australian,

. 17 July

A WA-based study into women's experiences of caesarean births has revealed worrying results. The study by Australian and Brit-ish universities followed 29 Austra-lian women having medically lian advi

that initial strong feel connection and concern baby had dissipated completely. completely. "Bables should remain in their mother's arms wherever possible." Darch mother Jenny Wheeler, 33, had both her children by Casertion

Hospital investigates caesarean death

ood said the h

'Extreme complications' at birth

By RICHARD BAKER and JULIA MEDEW

SUNSHINE Hospital is investi-gating the death of a Melbourne mother during a caesarean delivery at the hospital on "uesday. esday. Western Health's executive ecctor of medical services, Dr ark Garwood, said extreme mplications during a esarean delivery caused the oman's death. He said the

baby survived and was doing well and that the hospital was providing extensive support and counselling to the father. "We are deeply saddened by the mother's death. There are circumstances in which a small number of pregnancies are externedly high risk and despite every possible precaution, com-plications do occur," he said in a written statement.

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"On the basis of the av and the state in one vices, we ditor-General's report, we ed in the region of 17 birth tes rather than 12," he said.

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chief executive said his call for more services was of "utm-ance" to Sunshine mas facing " hospital's emergency artment, partly because of a of birth suites.

lack of birth nuise. "Birthing in the ED presents. clinical risks as the midwife must leave patients in the about ward to attend to the woman in emergency." he said. The report said a clinical assessment covered in an internal audit by Sunshine Hos-pital in 2011 had identified high clinical, financial and organisational risks due to the increased demand".

22

201

Today, rather than success being newsworthy, negative stories get the column inches.





Letters to the editor



Figure 1. This is an example of a ROTEM graph for a patient with normal clotting function.¹³

ROTEM and TEG are visico-elastic point

New use for an established tool

We read the recent 'Tools of the Trade' issue of *O&G Magazine* (Vol 17 No 4 Summer 2015) with interest and report here on the use of rotational thromboelastometry (ROTEM) and thromboelastography (TEG) in an obstetric setting.

Massive obstetric haemorrhage is a common and important emergency. In 2006–10, obstetric haemorrhage was the third-leading cause of direct maternal death in Australia¹ and the leading cause of maternal mortality and ICU admissions worldwide.^{2,3} In Australia, 1.28 per cent of women giving birth will require transfusion of two or more units of blood.⁴ In South Australia during 2013, 4.6 per cent⁵ of deliveries were complicated by postpartum haemorrhage (PPH) of more than 1000ml and, in Australia each year, six to nine women per 10 000^{6,7} will undergo emergency peripartum hysterectomies when other interventions fail.

Both intrinsic and extrinsic pathways to coagulation activation alter in pregnancy: pro-coagulation factors, such as fibrinogen, von Willebrand factor, factor IX, X, XII, VII, VIII increase; platelet count generally decreases; and anti-coagulation factors, such as tissue plasminogen activator (tPA), decrease.⁸ These changes overall confer a hypercoaguable state in pregnancy that increases with gestation.

The majority of PPH is secondary to tone, tissue or trauma. Coagulopathy can also be a primary cause, for example, consumptive coagulopathy associated with a severe abruption, or contributing factor associated with a dilutional or consumptive coagulopathy that subsequently develops. Correcting the pathophysiology to stop bleeding is important, including the correction of any coagulopathy. Conventional coagulation tests such as platelet count, prothrombin time (PT) and activated partial thromboplastin time (aPTT) have several limitations: it can take up to an hour to obtain results; they are performed on plasma rather than whole blood; and they cannot diagnose multi-factor coagulation defects.⁹ It has been reported that during massive PPH, PT and aPTT levels can remain normal despite 4500ml of blood loss.¹⁰ These tests are also insensitive to fibrinogen levels.^{3,8}

The conversion of fibrinogen to fibrin via the common coagulation pathway is essential to stable clot formation. Acquired fibrinogen deficiency is a major coagulation abnormality associated with PPH, with the fibrinogen concentration inversely proportional to blood loss volume.⁸ Fibrinogen levels less than 2g/l are associated with critical physiological derangement¹¹ and the need for massive transfusion.¹⁰ Fibrinogen levels can be performed, but can similarly take an hour to obtain results. of care tests, providing rapid functional assessment of coagulopathy, that have the potential to advance the management of coagulopathy associated with PPH. ROTEM/ TEG have been available in Australia for some years and are used in hepatic, cardiac and vascular surgery. Both of these tests measure individual components of haemostatic clot formation via intrinsic and extrinsic pathways, analysing clot initiation, clot strength, hyperfibrinolysis, platelet deficiency and fibrinogen level.⁸ They can also provide an indication of abnormalities of coagulation within ten minutes of testing. This potentially allows for more rapid, goaldirected replacement of coagulation products and minimises the use of blood products. The latter is important as it reduces risk of acute allergic reactions, transfusion-related acute lung injury and transfusion-associated circulatory overload.12

A representation of various clotting functions over time is provided as different graphs, which are interpreted and guide treatment.

Table 1. Clinica	l situations in	which	ROTEM/TEG	might be useful.
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Primary PPH where management in theatre is required
Other third-stage complications, for example, third/fourth-degree tears, manual removal of placenta, uterine inversion, associated ongoing blood loss >1500ml
Caesarean section associated with ongoing blood loss estimated >1500ml
Re-exploration for suspected haemorrhage within 24 hours of surgery
 Other obstetric conditions: Major placental abruption, for example, associated with IUFD or severe pre- eclampsia Ruptured uterus Suspect amniotic fluid embolism Severe pre-eclampsia-associated coagulopathy Septic shock associated with coagulopathy
After an intervention with coagulation product to assess response
First trimester ectopic pregnancy presenting with Class 3 shock
Major haemorrhage associated with inevitable abortion

deficiency.13

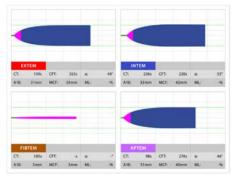
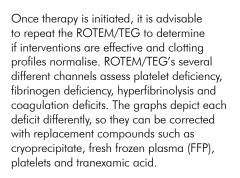


Figure 2. ROTEM graphs representing fibrinogen



Figure 3. ROTEM graphics representing thrombocytopenia.¹³



Fibrinogen deficiency

FIBTEM graphs depict fibrinogen deficiency.⁹ The correction of fibrinogen deficiency in Australia and New Zealand usually occurs with cryoprecipitate, although some centres are trialling the use of fibrinogen concentrate.

Platelet deficiency

Platelet deficiency occurs with volume loss or substrate deficiency. A decreased amplification curve on EXTEM shows platelet deficit.⁹ Comparing the FIBTEM and EXTEM graphs can distinguish fibrin deficiency from thrombocytopenia.⁸ A platelet transfusion can correct this deficiency.

Hyperfibrinolysis

Hyperfibrinolysis occurs when fibrinolytic activity is increased. It can compound

coagulation defects.⁸ ROTEM detects hyperfibrinolysis on the INTEM/EXTEM graphs via falling clot amplitude. It is detected by comparing EXTEM and APTEM.⁸ Hyperfibrinolysis can be treated with tranexamic acid (TXA), an antifibrinolytic agent that competitively binds to plasminogen, preventing it from binding to fibrin.

ROTEM does not detect disorders of platelet function, such as von Willebrand disease or anti-platelet activity related to drug use.⁹ ROTEM/TEG promises to be a valuable tool in managing coagulation deficits during PPH in the future.

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Table 2. Commonly used ROTEM channels in pregnancy.¹³

Test name	Reagent	Use
INTEM	Ellagic acid	Intrinsic pathway defects of coagulation activation
EXTEM	Recombinant tissue factor	Extrinsic pathway defects of coagulation activation
FIBTEM	Recombinant tissue factor and Cytochalasin D (platelet inhibitor)	Assesses for fibrinogen deficiency by blocking platelet contribution to clot formation
APTEM	Recombinant tissue factor and Aprotinin (fibrinolysis inhibitor)	Assesses for hyperfibrinolysis

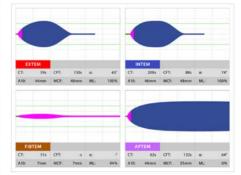


Figure 4. ROTEM graphics representing hyperfibrinolysis.¹³

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William Smellie

I very much enjoyed reading the historical piece by Prof de Costa in the recent O costaMagazine (p74 Vol 17 No 4 Autumn 2015). As always, with her wonderful prose, Caroline skillfully plunged the reader into years past, in this case the birth of the obstetric forceps. It felt as if I had been a primary witness of the very events that would, eventually, lead to the coronation of an 18-year-old Queen after whom both Caroline's State and my State are named. However, and there is rarely an 'however' with Caroline's beautiful writings, a single phrase leapt from the page with the abruptness of a Whig's opposition to a Jacobean king. The phrase?

'The great English obstetrician William Smellie....'

Such was the offense to a proud son of a fine Scottish midwifery training that I was moved to defend the posthumous honour of Smellie against the outrageous insult of being called English. Smellie was born in 1697 in Lanark, a modest but distinguished town in central Scotland. (As an aside, my own direct ancestor Sir William Wallace, Steward of Scotland, first raised his sword in anger against the English in Lanark in 1297). At the age of 25, Smellie entered medical practice in Lanark; only moving to London some 20 years later, in 1741, to establish a practice and to teach midwifery. This was a time of the Whig Supremacy when a political movement that was vehemently opposed to both Catholicism and the Stuart claim to the throne remained in power for half a

century. Britain's (still) longest serving Prime Minister, Sir Robert Walpole, a Whig, had just retired after 20 years at the political helm as Smellie took up residence in Pall Mall. Against this political backdrop, accent aside, living and working in London. Smellie would have been only too aware of his 'Scottish-ness'. A feeling, I am sure, to be more than somewhat heightened four years later when Prince Charles Edward Stuart, the Young Pretender, raised his standard at Glenfinnan to claim the Scottish and English crowns and catapult the two nations into bloody war once more.

It is certainly true that Smellie refined his clinical skills and matured as a 'great obstetrician' during his years in London and without that experience he would not have published his landmark contribution to our field A Treatise on the Theory and Practice of Midwifery in 1752. However, English? I think not. It was because midwifery was a central component of the Scottish medical education, but was something distinctly lacking from training south of the border, that Smellie had skills badly needed in London. But he was not English. Indeed, due to ill health, he fondly returned with his wife to Lanark in 1759, where he died four years later.

To close the loop, William Lamb (Lord Melbourne), another Whig Prime Minister and the last British Prime Minister to be sacked by a king (William IV), is best remembered in the UK for his loyalty and wise counsel to the young Queen Victoria in her early years of reign. In Australia, Lamb is immortalised by having John Batman's first European settlement on the Yarra named after him. As Prof de Costa noted, had the Princess Charlotte not had the 'dithering' English physician Sir Richard Croft attend her during her obstructed labour, but instead had had a skilled Scottish obstetrician present Melbourne, Victoria and Queensland would have had very different names. Alas, Smellie was dead and James Young Simpson, who would yet attend Queen Victoria as her physician in Scotland, was only six years old on that 'cold November morning in 1817' when Charlotte died. Vale Smellie – a great SCOTTISH obstetrician.

Prof Euan M Wallace AM

MBChB, MD, FRCOG, FRANZCOG, FAHMS Carl Wood Professor and Head of Department Director of Obstetric Services **Monash Health**

Author's response

Och aye, Euan, you are absolutely right. Please accept my humble apologies. As a Fellow of a Scottish College, I should have done better! And thank you for the detailed and fascinating history of Smellie's life, and the brief portrayal of his times, which I am sure will greatly interest readers.

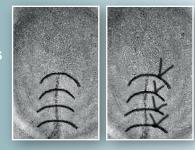
Prof Caroline de Costa AM

MBBS, PhD, MPH, FRANZCOG, FRCOG, FRCS (Glasgow) James Cook University School of Medicine



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In 2015, there were both **fictional** and **non-fictional** pieces addressing **a broad range** of women's **health issues** including anorexia, child marriage, pregnancy in third world countries, assisted reproductive technology and violence against women.



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Case reports

Successful pregnancy outcome after treatment for primary lung adenocarcinoma

Dr Michelle Englund FRANZCOG Department of Obstetrics and Gynaecology, Centenary Hospital for Women and Children

Prof Stephen Robson FRANZCOG Department of Obstetrics and Gynaecology, Centenary Hospital for Women and Children, ANU Medical School

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Dr Stephen Brazenor FANZCA Department of Anaesthesia, Calvary Hospital, ANU Medical School

Dr David Leong MB BS, FRACP Department of Medical Oncology, Canberra Hospital, ANU Medical School

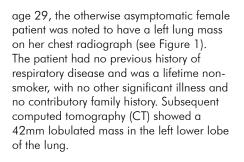
Dr Angela Rezo FRANZCR Department of Radiation Oncology, Canberra Hospital, ANU Medical School

Dr John Tharion FRACS Department of Thoracic Surgery, Canberra Hospital, ANU Medical School

The incidence of primary lung cancer in young women in Australia is extremely low, with only 42 cases in women aged less than 40 years diagnosed nationally during 2007, an age-specific rate of less than 0.7 per 100 000.¹ Concerns have been expressed that the combination of smoking in young women, increased maternal age during pregnancy and increasing incidence of lung cancer worldwide may cause an increase in pregnancy-associated lung cancers.²

Case report

During a routine screening medical examination before an overseas posting, at



After bronchoscopy and biopsy, a diagnosis of lung poorly differentiated adenocarcinoma was made. A positron emission tomography (PET) scan showed uptake in the primary in the left lower lobe and equivocal uptake in the ipsilateral hilar nodes. A left pneumonectomy was performed. The tumour was a 42mm poorly differentiated adenocarcinoma with perineural and lymphovascular space invasion. Three hilar nodes and one mediastinal node contained metastatic disease. The pathological stage was IIIA (see Figure 2).

Subsequent testing revealed the tumour was epidermal growth factor receptor (EGFR) negative and anaplastic lymphoma kinase (ALK) mutation positive. The patient was managed with adjuvant chemotherapy and radiotherapy. In consultation with the treating

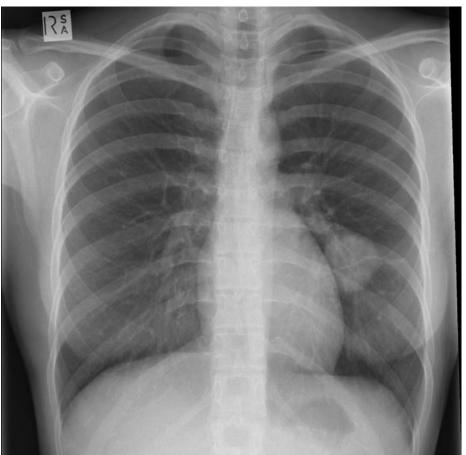


Figure 1. Chest radiograph revealing left lower lobe lung tumour.

team, she did not undergo fertility treatment to cryopreserve either oocytes or embryos.

Adjuvant radiotherapy was delivered to the mediastinum in order to reduce the risk of local recurrence. A conformal beam arranged was employed given a dose of 50.4 Gray in 28# over six weeks. The mean lung dose to the right lung was 4.6 Gray and the V20 was seven per cent. The risk of radiation pneumonitis therefore was low as was the risk of significant pulmonary fibrosis.

The patient did not recall disruptions to her menstrual cyclicity subsequent to the chemotherapy. She and her husband began actively trying for pregnancy and menstruation was regular in the lead up to pregnancy. There were no delays in achieving an ongoing pregnancy by which time the patient was 32 years old. During the first trimester, the patient was found to have a resting pulse of 100 per minute, oxygen saturation on room air of 98 per cent and blood pressure of 98/68 mmHg. There was tracheal deviation to the left.

By the second half of pregnancy, the patient had a six-minute walk distance 80 per cent of the predicted value for age and significant oxygen desaturation with exercise. Echocardiography was difficult post-pneumonectomy. At one point, she developed an upper respiratory tract infection and became very breathless. By 26 weeks of gestation, oxygen saturation was 98 per cent on room air, pulse 92/ minute and she had no clinical features of right ventricular strain, with the chest clear to auscultation. Obstetric progress was normal, with no maternal hypertensive, diabetic or other complications. Fetal ultrasound surveillance revealed growth on the 26th centile, but normal umbilical Doppler signatures.

After a multidisciplinary discussion between the treating team, the patient was delivered by elective caesarean section under general anaesthesia at 36 weeks of gestation. The choice of general aesthetic over a regional approach was made on the basis that the patient had a reasonable exercise tolerance and the availability of Sugammadex meant that muscle relaxation could be completely reversed at the end of the procedure. Potential intraoperative and postoperative disturbance of respiratory muscle function with a regional anaesthetic was thought to be associated with greater risk. The patient had an unremarkable postnatal recovery and the baby, a boy weighing 2.57kg (just above the 25th centile for gestation) was in good condition and normal, and subsequent development to six months has been unremarkable.

Discussion

A review of all cases of lung cancer during pregnancy registered in the international Cancer in Pregnancy registration study (CIP study: www.cancerinpregnancy.org) reported only nine cases in total.² The reports originated from four European centres, with patients having a median age of 33 years (range, 26–42). The median gestational age at diagnosis was 17 weeks, but ranged from six to 28 weeks. All of the nine patients presented with distant metastases to sites including bone, lung, brain, spinal cord, pleura, lymph nodes, adrenals and liver. Histopathology was compatible with adenocarcinoma in four patients, non-small cell lung cancer with unidentified subtype in two patients, and squamous-cell, large-cell undifferentiated and poorly differentiated carcinoma in the remaining three patients. The maternal postpartum outcomes were poor, with less than one year survival following delivery. One of the patients

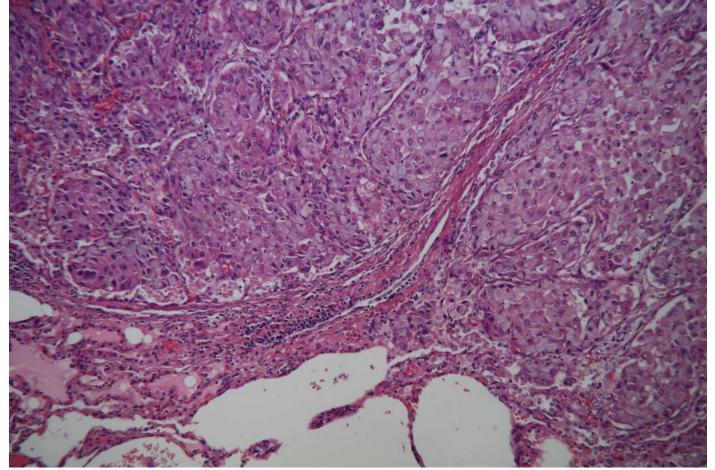


Figure 2. Tumour histology revealing poorly differentiated adenocarcinoma with perineural and lymphovascular space invasion. (H&E staining, 40x).

experienced a miscarriage, and three of the pregnancies were terminated. Of the five remaining babies, all were delivered preterm by caesarean section because of poor maternal status, with the median gestational age at 30 weeks (range 26–33). The authors concluded that 'lung cancer in pregnancy has a dismal maternal outcome in our series.'

One subsequent case report from Portugal described that case of a 36-year-old woman, a known smoker, diagnosed with metastatic lung adenocarcinoma of the left lung at 27 weeks of gestation.³ She was delivered by caesarean section at 29 weeks gestation, then received a combination of chemo- and radiotherapy. The authors reported a progression-free survival of nine months, but the patient died 19 months after first diagnosis.

The only case report similar to our patient is from Japan and was published in 1994.⁴ That patient was 25 years old, and underwent right middle lobectomy for welldifferentiated papillary adenocarcinoma followed by adjuvant radiotherapy. Five years after treatment, she conceived and delivered a healthy child, then had another child two years later.

Pregnancy management for a woman with previous stage III primary lung adenocarcinoma, managed by pneumonectomy has not been reported in the literature. There are reports of successful pregnancy in women with only one lung following treatment for benign conditions, such as tuberculosis and bronchiectasis; however, they do not have the burden of postoperative radiotherapy. A study of 80 women who had undergone pneumonectomy for benign disease during the period 1947–54 reported: 'pneumonectomy for a nonprogressive disease of one lung in a woman of childbearing age is associated with a nearly normal obstetric history and life expectancy.'5 A similar study of 47 women who had lost a lung to benign disease, published in 1967, concluded 'all reports of pregnancy after pneumonectomy have confirmed the prediction that this added burden does not prove troublesome either during pregnancy or at the time of delivery."

Conclusion

Lung cancer in women of reproductive age is extremely uncommon, with only 11 other cases reported in the literature. When the diagnosis is made during pregnancy, the prognosis is uniformly poor. For cases of primary lung cancer diagnosed and treated successfully before pregnancy, the outlook for the mother and baby appears good.

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- 3 Neves I, Mota PC, Hespanhol VP. Lung cancer during pregnancy: an unusual case. *Rev Port Pneumol.* 2014; 20(1): 46-9.
- 4 Satoh H, Yano H, Yazawa T, Hasegawa S. Successful pregnancy after curative therapy for advanced lung cancer. *Chest.* 1994; 105 (1): 307-8.
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- Gaensler E, Strieder J. Pregnancy following pneumonectomy. Ann Thorac Surg. 1967; 4 (6): 581-97.

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

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

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



Endometriosis in the inguinal canal

Dr Phillip Jeans FRACS

Prof Stephen Robson FRANZCOG

A 39-year-old woman was referred with the problem of cyclic right inguinal pain. She had two children, aged seven and five years. The first had been delivered by caesarean section for obstructed labour, the second by elective caesarean delivery. She and her partner had been trying unsuccessfully for a third child for almost a year, with no success. The menstrual periods had become heavier and more painful over that time.

The right groin lump was generally uncomfortable, but the pain reached

a crescendo just before and during menstruation. On examination, a tender inguinal swelling was palpable on the right and was initially thought to be an inflamed lymph node. The patient was otherwise healthy and well, with an unremarkable past history. Imaging suggested a hypodense discrete bilobed lesion within the inguinal canal (see Figure 1). A plan was made for laparoscopy and evaluation of fallopian tube patency then an inguinal exploration.

Laparoscopy revealed endometriosis with a large deposit of endometriosis associated with a right tubo-ovarian mass, which was excised. Within the right inguinal canal was a firm discrete mass involved in considerable scarring and adherent to the inferior epigastric vessels (see Figure 2).

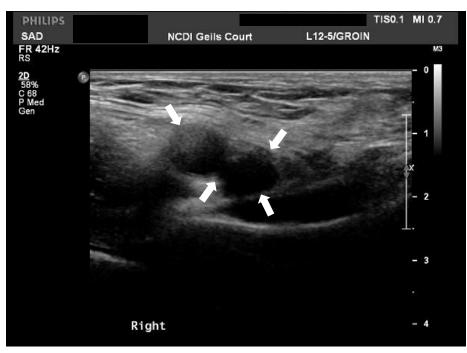


Figure 1. Ultrasound image showing a tender, bilobed hypodense lesion in the right inguinal canal.



Fellows and Diplomates of the College, along with Senior Registrars, are invited to express their interest in participating in a review of CLIMATE online resources.

As part of the College's online content review cycle, a review of the CLIMATE online resources for the Certificate of Women's Health (CWH), Diploma of the RANZCOG (DRANZCOG) and the Advanced Diploma of the RANZCOG (DRANZCOG Advanced) training programs has commenced. The College is looking for content experts to review the online material for clinical currency. Some of the material sits on the CLIMATE system, while other material is accessed via links to external websites. Access to the internet is required to participate.

This activity is eligible for CPD Points in the CPD Online program - Academic Abilities domain.

If you are interested in being involved in reviewing a curriculum topic area of the online material for clinical currency, please contact Ms Angela Chan via email achan@ranzcog.edu.au





Figure 2. Dissection of the right inguinal canal following laparoscopy, revealing a dense lesion (arrowed) adherent to the inguinal vessels.

The lesion was carefully dissected free and the incision closed. The patient developed a groin haematoma post-operatively that was drained then settled with conservative measures. Histology revealed the inguinal lesion to be typical endometriosis.

Discussion

While pelvic endometriosis is very common, presentation of endometrial deposits outside the peritoneal cavity is very rare and can cause considerable diagnostic uncertainty. Reports have been published describing endometriosis in the diaphragm, lung and pleura, as well as the kidney and ureter, and even the extremities. Possible mechanisms

for development of ectopic endometrial tissue at these sites include metaplasia and lympho-haematogenous spread.

Endometriotic deposits in the inquinal region are very uncommon, accounting for less than 0.5 per cent of all cases.¹ More than 50 cases have been described in the literature.² The typical presentation is similar to that in our patient, with cyclic pain and swelling in the groin, although some cases have been painless and in such cases the diagnosis is rarely suspected pre-operatively. Interestingly, the great majority of cases of inguinal endometriosis have been unilateral and occur on the right side as was the

case in this patient.² The reason for this is unclear, but may relate to a supposed clockwise circulation of peritoneal fluid and atypical lymphatic vessels that are more common on the right.^{2,3} The round ligament is often 'protected' by the sigmoid colon on the left and this may alter access for ectopic endometrial cells.

There is an association between inquinal endometriosis and groin hernias – typically inquinal hernias, which in themselves are less common in women – and this coexistence has been noted in up to 40 per cent of cases.⁴ Malignant change has also been reported⁵ and one of us (PJ) has been involved in such a case in the past, and so excision of suspected inguinal endometriosis en bloc is typically undertaken. There is a strong association with intraperitoneal endometriosis, as seen in this case, so concurrent gynaecological involvement and laparoscopy is recommended when inguinal endometriosis is suspected.

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- Klein AE, Bauer T, Marks K, et al. Papillary 5. clear cell adenocarcinoma of the groin arising from endometriosis. Clin Orthop Rel Dis. 1999; 361: 192-8.



Targeted resources aimed at health professionals who see women that are pregnant, planning a pregnancy or breastfeeding.

Women Want to Know has been developed by the Foundation for Alcohol Research and Education (FARE) in collaboration with the Australian Government Department of Health, Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), the Australian Medical Association (AMA), and a number of other agencies.

The RANZCOG course is available via CLIMATE and attracts CPD points in the self-education category.

uria Meetings

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ACTIVITY 🌡 FOR 🛈 FURTHER INFO

ORTUNITIES AT RANZCOG OPP Research Project Assessor

All Trainees entering the FRANZCOG training program are required to present a search project that meets defined satisfactory completion criteria before gaining eligibility for evaluate to Fellowship. Assessors are needed to assess research projects.

🔒 Fellows Ideldin@ranzcog.edu.au

Specialist International Medical Graduates (SIMG)

* The SIMG Assessment Committee has initiated a mentoring program for SIMGs on Mentoring Program

- a trial basis. Fellows are required to become mentors. https://www.ranzcog.edu.au/the-simg-mentoring-program.html
 - Sellows

(i)

A Training Supervisors for the FRANZCOG Training Program (Core/Advanced) are an integral part of the Training Program. All Training Supervisors must be a Fellow and employed at a RANZCOG accredited training hospital. The Fellow may be a full-time or part-time staff specialist or, where appropriate, a Visiting Medical Officer (VMO). They are responsible for the overall supervision and mentoring of the Core/Advanced

Training Supervisors are responsible for conducting the Formative Appraisal (three-monthly) and Summative Assessments (six-monthly) of their Trainees using the

appropriate RANZCOG forms.

Fellows

 smccarthy@ranzcog.edu.au or https://www.ranzcog.edu.au/training-supervisors.html

Ultrasound Workshop Facilitator/Tutor This full day practical workshop focuses on the knowledge and skills that RANZCOG registrars require to complete the ultrasound IHCA. The five hours of practical hands-on scanning includes training in transabdominal and transvaginal imaging using a combination of pregnant women and pelvic phantoms. Five workstations are organised which enables interactive small group teaching. Each workstation has a pregnant volunteer, an experienced tutor and a Sonosite ultrasound

machine. Tutors are required.

- Fellows pholmes@ranzcog.edu.au

ANZJOG

Reviewers are required for manuscripts submitted for publication in ANZJOG under the direction of appointed Associate Editors.

i sortenzio@ranzcog.edu.au

Global Health Volunteer Register

- \mathscr{F} All members of the College are invited to nominate for voluntary work opportunities in the Pacific Island Countries by joining the Register of Volunteers.
- (i) cwalker@ranzcog.edu.au

Expert Witness Register

The RANZCOG Expert Witness Register provides an opportunity for Fellows to nominate an area of practice in which they are willing to provide expert medico-legal opinion. The Register facilitates contact between these Fellows and legal organisations seeking medico-legal opinion for specific obstetric and gynaecology cases.

http://www.ranzcog.edu.au/the-ranzcog/expert-witness-register.html

Friends of the College

The Friends of the College Collection was established in 1989 to raise funds to support the ongoing costs of developing, maintaining and conserving the College Collection. Membership of the Friends by donation is open to College members as well

as those in the wider community with an interest in history of medicine, women's health, 🚣 Members

http://www.ranzcog.edu.au/the-ranzcog/historical-collections/college-collections/friends-of-the-college-collection.html

7



Elections are held every two years for positions on the GP Obstetrics Advisory Committee. Five positions, including two Intrapartum Care representatives and three Shared Care representatives, are required for this committee. Information will be circulated according to election schedules.

 Election process, pgriffiths@ranzcog.edu.au, GP Obstetrics Advisory Committee, vspark@ranzcog.edu.au

RANZCOG Council

Elections are held every two years for positions on the RANZCOG Council. Information will be circulated according to election schedules.

- Religion with the original fellows, Trainee, Community Representatives, Diplomates () pgriffiths@ranzcog.edu.au

Regional Committees

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- pgriffiths@ranzcog.edu.au

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- smccarthy@ranzcog.edu.au

Fellowship Updates

Fellowship Updates are held twice a year in many provincial centres through out New Zealand on a range of topics. Fellows with special expertise/knowledge are invited to share with other Fellows.

- Fellows

(i)jcumming@ranzcog.org.nz

IMG selection panels

A The College relies on the willingness of individual Fellows to give of their time in order to conduct many of its core activities, including the assessment of international medical graduates. Become a member of an international medical graduate panel.

- 🚣 Fellows
- (i) jcumming@ranzcog.org.nz

MCNZ roles

A From time to time, the Medical Council of New Zealand seeks representation for various performance assessment committees and reviews.

- 🚣 Fellows
- jcumming@ranzcog.org.nz

Practice Visitors

The NZ Committee manages a practice visit program unique to New Zealand and RANZCOG. Fellows of RANZCOG are able to receive a practice visit as part of their continuing professional development. The program is currently seeking practice visitors to be part of a team in reviewing a Fellows practice.

i jkaveney@ranzcog.org.nz or https://www.ranzcog.edu.au/new-zealand/practice-visits.html

Medical Careers Expos

A Do you have a few hours to spare (expos are generally held on a weekend) to spend some time providing information on the speciality to undergraduates Members

 Contact your local Regional/NZ office for information on upcoming opportunities. Keep an eye out on information circulated via Collegiate, specific regional notices and news items on regional sections of the RANZCOG website.

Retired Fellows

Regional Committees run activities for retired Fellows at various times. Fellows

 Keep an eye out on information circulated via Collegiate, specific regional notices and news items on regional sections of the RANZCOG website.

Five years on: the PANDA Helpline



Terri Smith BA, PostGradDip CommDev, Masters Soc Sci, GAICD CEO Perinatal Anxiety & Depression Australia

At least one-in-seven new mothers and one-in-ten pregnant women in Australia will experience perinatal depression. Data on perinatal anxiety are less reliable; however, perinatal anxiety is thought to be at least as common as depression and many women experience both anxiety and depression. Fathers are also affected by perinatal anxiety and depression. The most recent data available from the Australian Institute of Family Studies suggest as many as one in ten new fathers will experience postnatal depression. We have recently had the opportunity to review data from the first five years of the Perinatal Anxiety & Depression Australia (PANDA) Helpline. The results, together with insights from our dedicated helpline team, present a compelling picture of this common and serious health issue that, in our view, is not discussed openly or often enough.

While PANDA has existed in Victoria for almost 30 years, the National Helpline only began in 2010. We have now managed more than 50 000 calls through the Helpline. PANDA is committed to sharing the essence of the stories we hear each day to improve service provision. There is one overwhelming message from the many conversations we have each week. Expecting and new parents do not anticipate perinatal anxiety or depression will affect them and, as a result, they are slow to recognise the symptoms, slow to seek help and, therefore, suffer longer than they need to.

With help, most women will fully recover from perinatal anxiety and depression. Obstetricians are well placed to help women anticipate and understand changes in their mental health. Understanding what is happening to them allows women to seek help early. This is important not just for the woman, but also for her baby and other family members.

PANDA Helpline

Calls to the PANDA Helpline cover the whole spectrum of emotional health and mental illness. While many calls focus on

Table 3. Who calls PANDA: by stage of pregnancy/time after birth.

Pregnant	1st trimester	7.2%	Total antenatal
	2nd trimester	8.2%	22.4%
	3rd trimester	7%	
After birth	Premature baby	0.6%	Postnatal to one year
	0–3 months	24.4%	54.1%
	4–6 months	13.1%	
	6–12 months	15.9%	
	more than one year*	23.6%	More than one year 23.6%

*Includes callers reflecting on a much earlier experience

difficulties associated with the transition to parenthood and low-level anxiety and depression we also deal regularly with acute mental illness and crisis-intervention calls.

PANDA's counselling team is an integrated workforce of professional counsellors and highly trained volunteers. To respond effectively to the diverse range of calls, all staff are trained in dealing with suicide prevention, domestic violence and trauma from childhood abuse.

Importantly, PANDA's service is more than an incoming helpline. For callers with mild-to-moderate perinatal anxiety and depression we also offer a follow-up service. This is a particularly important service given the volatile nature of the perinatal period.

Who calls PANDA?

While most calls to PANDA are directly from women experiencing perinatal anxiety and depression, the calls are also

Table 1. Who calls Panda: by category.

Caller category	Percentage of total calls 2014–15
Consumer	86.5%
Partner	5.5%
Family/friend	4%
Health professionals	4%

Table 2. Who calls Panda: by age range.

Age of callers	Percentage of total recorded	Aust Births 2012 *
Under 24	12%	17%
25–30	28%	28%
31–35	33%	33%
36–40	19%	18%
41 plus	8.5%	4%

*Australian Mothers and Babies, AIHW, 2012

from partners (5.5 per cent), other family members and friends (four per cent) and the remaining four per cent from health professionals (see Table 1). PANDA's team welcomes calls from health professionals to consult about a patient or provide referral options and resources.

Table 2 compares age of callers with the average age of birth in Australia. Younger mothers are under-represented in our callers and older mothers somewhat overrepresented. We know that older mothers often have a complex journey to birth (such as miscarriage, IVF or birth trauma), which is a recognised risk factor for perinatal anxiety and depression.

Most calls are from women in the postnatal period. We would like to see an increase in calls from women during pregnancy. The group calling more than one year after the birth includes those who have delayed treatment and those still recovering. This category also includes callers who may have been triggered by our awarenessraising activities and are understanding for the first time that there is a name for the experience they had in the past.

While the great majority of callers to PANDA are women, there is an encouraging increase in recent years in the number of male callers. This increase is linked to two factors, firstly PANDA's direct efforts to increase male callers, including the launch and promotion of howisdadgoing.org.au, a website specifically targeting new fathers and, secondly, a change in clinical practice whereby helpline staff routinely ask about how the non-calling parent is managing and encourage them to call if they need assistance. Of the male callers, most (65 per cent) are calling about their concerns for their partner while 35 per cent are calling about their own experience of depression or anxiety.

Callers come from right across Australia, although there remains a small overrepresentation in Victoria. At just 13.5 per cent of PANDA's callers, Queensland is under-represented. To match Australian population data this figure should be closer to 20 per cent.

Figure 1 shows the spread of callers across capital city and non-capital city areas. Representation of rural callers in Victoria and NSW exceeds population average and in Queensland, Tasmania and South Australia it closely matches population. There is room to improve rural access in Western Australia and the Northern Territory.

Most callers to PANDA do not have a specific diagnosis of perinatal anxiety and depression and PANDA does not diagnose a caller's mental health status. PANDA's general assessment process shows 54 per cent of callers with mild-to-moderate anxiety or depression and the remaining 46 per

Tips for managing your patients

Emotional well-being in pregnancy is important to consider and respond to. At least one-in-ten expecting mothers will experience antenatal depression or anxiety. While it might be normal for an expecting mum to feel sad or a little anxious about pending parenthood, symptoms of depression or anxiety that persist for more than two weeks should be addressed.

Of women diagnosed with postnatal depression or anxiety at 12 weeks post-birth, 40 per cent report having experienced symptoms antenatally.³ There is an opportunity to ensure these women get help sooner rather than later.

Try to make the time and create the space to check in on your patients' mental health and emotional well-being as well as their physical health and well-being. Early intervention reduces suffering and gives the baby the best chance of thriving. In some cases, at the most serious end, early intervention can save lives. In particular, watch out for signs of anxiety. Perinatal anxiety is less well understood than depression. An expecting mother's distress during pregnancy can affect the baby's development and also the birth experience. Traumatic birth experience is a risk factor for postnatal mental illness. It is also important to note that, while many expecting mothers have heard of postnatal depression, many do not understand that antenatal depression is almost as common.

Previous mental illness is a significant risk factor for perinatal anxiety and depression, so it is important that women with a history of mental illness are effectively monitored for perinatal anxiety and depression during their pregnancy and after the birth. Make sure you know about any history and check in regularly with patients about their mental health. Refer any patient with a history of mental illness who is presenting with symptoms that are affecting functioning to a perinatal psychiatrist for review and management before the birth.

You can contribute to breaking down the stigma attached to mental illness by routinely asking questions about your patients' mental health. Given the volatile nature of the perinatal period, it is important to check in regularly with patients about their mental health. With increasing understanding of the direct and indirect impact of perinatal anxiety and depression on expecting and new fathers, you might also attend to signs that the male partner is struggling.

Have perinatal anxiety and depression resources available in your practice. This will also help normalise the experience so that your patients can talk about it and seek help. You and you staff are welcome to contact PANDA for specific advice and for resources.

PANDA Helpline 10am – 5pm EST Monday to Friday 1300 726 306 www.panda.org.au

In addition to receiving incoming calls, PANDA is able to provide a callback service to support women through this difficult time. The service is free and confidential. No referral is necessary. PANDA has an extensive referral database and is able to make sure callers are linked to local services.

Obstetricians are welcome to call the PANDA Helpline for secondary consultation or general advice.

cent in the moderate-to-severe category (see Figure 2). Caller needs range from simply seeking information and reassurance to immediate crisis intervention.

While 53 per cent of callers had no prior identified mental illness, 47 per cent identified a previous history of mental illness (see Figure 2). We know that previous mental illness is a risk factor for perinatal anxiety and depression, but previous mental illness is over-represented in PANDA callers. It is probable that these callers have been able to identify their declining mental health and may be confident in seeking help given their prior experience of mental illness.

Lessons learned

Perinatal anxiety and depression doesn't discriminate – it affects women from across the socioeconomic spectrum. Many women are reluctant to seek help or simply don't understand what is happening to them. Of callers to the PANDA Helpline, 65 per cent report having symptoms for more than four weeks before, including 15 per cent who have had symptoms for more than a year.



Figure 1. Caller location by region.

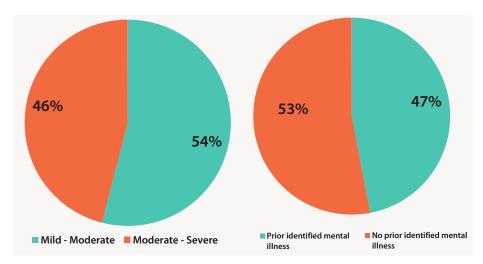


Figure 2. Callers by severity of depression (left) and history of mental illness (right).

Callers often feel a deep sense of shame or judgement – this is commonly coupled with a view that they don't deserve to be a parent/are a bad mother. For some, this leads to thoughts that someone will take their baby away if they talk about how they are feeling. Sometimes, women believe their family will be better off without them.

Our callers often do not tell their primary health professionals about their experience of perinatal anxiety and depression: 71 per cent of callers in our most recent audit period had not told their GP about their symptoms before calling the Helpline.

Grief and loss are significant contributing factors to perinatal distress. More than 50 per cent of callers say these experiences (including IVF, miscarriage, stillbirth, relationship breakdowns and complex trauma) contributed to their capacity to be present in their pregnancy or to their baby. The most important lesson we have learned is that seeking help early is the best option to help women recover and develop a healthy relationship with her baby. Many women need help to understand what is happening to them and encouragement to seek treatment. Letting a patient know that perinatal anxiety and depression is very common and treatment is available is a powerful step.

References and further reading

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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.

resources team. I would start by requesting a meeting with Dr Jones to discuss her behaviour and the negative effect it has been having on one of the Trainees for whom I am a RANZCOG Training Supervisor. I would also discuss the roster clashes with the Head of Department to avoid putting this Trainee and others in the impossible situation where they are expected to be in two places at once.

When I met with Dr Jones, I would explore her recollection and understanding of the situation and enquire whether she felt her behaviour was acceptable. If Dr Jones' recollection was completely different, then, with the permission of Dr Jones and the Trainee, I would need to make some further enquiries. I could make these enquiries myself, as the Training Supervisor, or escalate to the Head of Department if I was not comfortable doing so. I would also discuss the practical issues of the roster with Dr Jones and that, where possible, we would change the timetable.

If the Trainee's concerns were substantiated, I would then talk to Dr Jones about how her behaviour, both her direct communication with the Trainee and also her indirect communication via negative comments to others, was consistent with bullying and that this behaviour was having negative effects on the Trainee. Bullying behaviour is often verbal and is repeated and unreasonable. I would explain that this behaviour is not appropriate or acceptable and further explain how the Trainee had been adversely affected by it.

I would ask Dr Jones to consider changing her behaviour and remind her that, in addition to being a teacher and trainer, she is also a role model for our Trainees. I would explore whether there were any underlying issues making her behave disrespectfully and whether she needed any assistance in changing her behaviour.

If Dr Jones was not open and receptive to what I was saying, I would need to take the issue of her bullying behaviour through a more formal process and notify the Head of Department. Usually this would be progressed through human resources and would typically involve the use of a mediator and then working through a performance management process.

Although bullying such as this, which occurs in the workplace, is the employing authority's responsibility to manage, as Dr Jones is a Fellow undertaking College business (in terms of training, supervision and assessments of the Trainee), RANZCOG could also be notified of any such allegations in order to provide support and advice and decide whether further investigation was required. RANZCOG has two 'contact officers' for this purpose; the Director of Education and Training, and the Training Services Manager. For more information, see the College's Bullying, Harassment and Discrimination in the Workplace Policy.

Q 'Dr Smith is in her second year of training and recently met with you, her Training Supervisor, for her formative assessment. She revealed she had not enjoyed the last three months as one of her supervising specialists, Dr Jones, frequently belittled her in front of others and criticised her for being late, even though she was required to complete the post-acute ward round before the clinic starts. She also reported that others had told her that Dr Jones often made negative remarks about her in front of other staff. What advice would you give Dr Smith as Training Supervisor and how would you manage the situation?'

Dr Sarah Tout FRANZCOG

А.

I would start by thanking Dr Smith for attending her feedback session and for specifically sharing this information with me. I would explain how sorry I was that she had been unhappy over the last few months, particularly as this had been the what appeared to be unacceptable

result of what appeared to be unacceptable behaviour demonstrated by a senior consultant within the department. I would ask Dr Smith to talk through the details, including giving instances of when and what had occurred, and try to explore the extent of the effect of this on her well-being. I would determine if Sarah knew if Dr Jones was aware she was upset and whether she had spoken directly to Dr Jones about her concerns. I would also enquire whether she felt this was affecting her performance at work and/or her training, and if some leave may be required while we worked through the issues.

Bullying behaviour causes emotional distress, but can also lead to psychological illnesses, such as anxiety, depression and insomnia, and its effect should not be underestimated. I would recommend Sarah consider contacting the free and independent counselling service available to her through her employing hospital. It is important that Sarah has some professional input into her well-being; her general practitioner or an occupational health advisor would be alternatives. I would make arrangements for a follow-up meeting with Sarah to see how she was feeling and whether she felt the situation was improving. In such a scenario, a mentor would be a valuable resource for Sarah. If she did not already have one, and she agreed, I would assist her in exploring this as a possibility.

Here the consultant is in a position of power over the Trainee and often, for this reason, bullying and intimidation may go unreported. This type of behaviour is unacceptable between two work colleagues from an employment perspective and is also not tolerated by RANZCOG. The ITP Coordinator or the Clinical Director can always be involved if you, as local Training Supervisor, feel you need additional support.

Ideally, these behavioural issues would be addressed directly with Dr Jones in a supportive and collegial way, but, if unsuccessful, it could become necessary to take a more formal approach through the hospital's human

Strengthening the rights of rural women in Fiji

to good effect in my new roles. I still work as an academic at the Fiji National University and Lautoka Hospital. However, my main focus now is to empower women and girls about their reproductive health as their basic human right. The political uncertainties in Fiji since 1987 have led to a health system that has become progressively less effective, owing to loss of human resources to other countries and a health budget that is stretched to provide essential services.

In spite of many decades of concerted effort by the Ministry of Health and its development partners – such as the UNFPA, Secretariat of the Pacific Community (SPC) and the World Health Organization (WHO) - the health indicators suggest marginal or no improvement. The contraceptive uptake rate (<40 per cent) is low with consequent high rates of unplanned pregnancies, particularly in rural areas, high teen pregnancy (ten per cent of all deliveries), sexually transmitted infections and female cancers.¹ All these factors contribute significantly to the disempowerment of women and girls, which is a major reason for their vulnerability to the discrimination and violence perpetrated against them.

Mortality associated with noncommunicable diseases (NCDs) remains high at 82 per cent of all adult deaths, many of which are premature. Overall average life expectancy of 64 for males and 69 for females is low and days lost from work owing to illness high.² The country's Ministry of Health conducted a WHO STEP survey³ in 2002, repeated in

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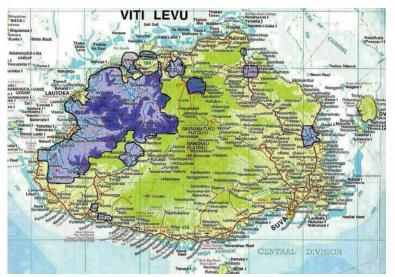
A/Prof Swaran L Naidu DSM, Dip Obs, FRANZCOG Fiji National University Medical Director Viseisei Sai Health Centre

Women's health has been a passion for me ever since I graduated as a doctor from the Fiji School of Medicine in 1978. After an internship and a stint in community health, I joined the obstetrics and gynaecology department at the Colonial War Memorial Hospital in Suva. I was fortunate to be a student of Dr Mary Schramm, an iconic figure in women's health in Fiji. Dr Schramm was passionate about her work, a great teacher and an excellent role model. She emphasised the basics in understanding clinical medicine and was compassionate and dedicated to her work in Fiji.

In 1986, I was fortunate enough to receive a WHO fellowship to go to Wellington for a year to do the Diploma in obstetrics. On my return, I worked in Lautoka until the military coup in 1987. I was committed to becoming a specialist in obstetrics and gynaecology. This led me to National Women's Hospital in Auckland and then, in 1990, to the Royal Hospital for Women in Sydney.

Life was not easy for overseas-trained doctors. While my traineeship was being organised, I worked as a research fellow in menopause under the mentorship of Drs Barry Wren, John Eden and Michael Webster. After completing my membership exams in 1994, I continued at the Royal as a senior registrar and, on obtaining Fellowship, joined the academic unit with Prof Michael Bennett, Drs Leo Leader and Steve Horowitz, where I stayed until 2011.

In 2011 my husband, Rajat Gyaneshwar, and I started a charitable trust to run the Viseisei Sai Health Centre (VSHC) in Fiji and we continue to work here. My strong background in clinical obstetrics and gynaecology, research and academic interests is being put



Areas covered in Viti Levu, Fiji (in purple) under the reproductive health outreach education and clinics project.



The author talks to schoolgirls as part of the outreach project.

2011, which reported the common NCDs in Fiji: hypertension with prevalence rates of 24.2 per cent in 2002 increased to 31 per cent in 2011; diabetes at 19.6 per cent in 2002 increased to 29.6 per cent in 2011; and obesity at 58.5 per cent in 2021 increased to 66.9 per cent in 2011. Adult motility in Fiji is three times higher than in Australia and New Zealand. These worsening NCD rates are alarming, but can be prevented and reduced by modifying lifestyle factors, as shown in other countries.²

In 2008, the United Nations Development Project (UNDP) Pacific Centre reported that the basic needs poverty has increased and their economic modelling predicts a worsening trend in rural households in Fiji. Using this it is estimated that 50 per cent of households in rural communities will experience basic needs poverty.⁴ Poverty is exacerbated by early deaths and disability caused by NCDs as well as lack of employment opportunities and lost educational opportunities owing to unplanned pregnancies, particularly in teenagers. Data from VSHC project have shown, in rural women, the higher the number of children the greater the number of unplanned pregnancies. This is a manifestation of their disempowerment,

owing to the lack of adequate information and awareness about contraception. Violence against women is high, with 64 per cent of women in Fiji reporting they have been in an intimate relationship having experienced violence in their lifetime.⁵ In this context, I have a strong commitment to the education of women and girls about their reproductive health as well as the Viseisei community in wellness and NCD prevention.

I have just completed a project funded by the European Union, under its human

rights instrument⁶, in which our team went out to remote villages and settlements to educate, provide counselling and clinical services in reproductive health. We have conducted a study to identify gaps in knowledge, attitudes, practice and barriers to look after their reproductive health, especially in regards to safe sex and cervical cancer screening.

More than 70 per cent of a total of 1505 rural women surveyed in a baseline survey conducted by the VSHC had no knowledge of reproductive health issues

Education in reproductive health	No. of participants	
Total number of participants from outreach/workshops/seminars for education	11103	
Youth workshops	161	
Education in schools	2083	
Faith-based workshops	254	
Teachers' workshops	178	
Women's advocates workshops	149	
University students	243	
Community health worker training	93	
Nurses' workshops	52	

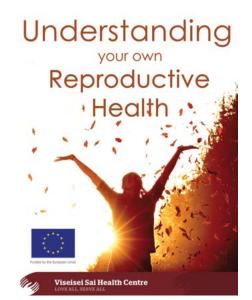
Table 1. Educational activities: February 2013 to December 2014



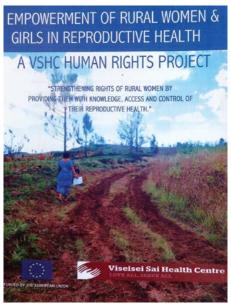
Consulting in the privacy of the mobile clinic.



The Cancer Society's mobile clinic used by the VSHC team for the outreach clinical work.



VSHC has taken the lead in local education efforts and outreach.



VSHC, with European Union funding, has been undertaking and publishing regional research.

such as cervical cancer and its prevention. This project has been about empowering women to exercise their health rights by providing them with information and outreach clinical services in family planning and contraceptive use.

Through the project, the VSHC has

provided rural women and girls with access to information on reproductive health, conducted 161 outreach clinics and provided educational and clinical services to more than 11 000 rural women and girls. Apart from clinical services, counselling and educational workshops, the centre has also conducted awareness

campaigns on reproductive health with various groups, including men and boys. Reproductive health is a human right denied to many women and girls because of gender inequality, lack of information and their ability to make informed choices about themselves. This leads to serious consequences for a woman, her ability to



Educational outreach activities take place under a shady tree.

realise her full potential and participate in society fully.

Cervical cancer is a preventable cancer, yet it is very common in Fiji. There are more than 100 new cases each year presenting late when a cure is not possible. During this project, 4013 pap smears were conducted and several women were identified with the early stages of the disease when a cure was possible. Follow up of abnormal Pap smear results was conducted by the team, to ensure adequate treatment.

These last four years have brought me back to where I started. Empowerment of women is crucial not only to better reproductive health but also to gender equality and advancement of the societies. There is a huge amount of work to be done to empower women and these efforts will continue.

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- 4 Narsey W: https://narseyonfiji.files. wordpress.com/2012/03/gender-issuesin-employment-underemployment-andincomes-in-fiji.pdf.
- 5 Fiji Women's Crisis Centre data

"Somebody's life; Everybody's business" 2013.

6 Empowerment of Rural Women & Girls in Reproductive Health; a VSHC publication, www.viseiseihealth.org.

Overall outputs of the project

From 5 November 2012 to 31 December 2014, the project has provided information and education on reproductive health (RH) rights, gender equity and key issues to girls and women.

- 11 103 individuals had education and information provided in RH.
- 1130 advocates trained via workshops.
- 5622 women and girls were provided with RH clinical services.
- 1557 girls and women counselled on contraceptive use and services were provided to those who required them.
- 5333 had breast examinations performed.
- 4016 Pap smears performed for cervical cancer screening.
- 455 women with complicated gynaecological or other problems were referred to the base hospital or VHSC specialist clinic for further specialist services.



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CLIMATE e-learning.

The RANZCOG Provincial Core Training program

Dr Anthony Geraghty FRANZCOG Chair RANZCOG Provincial Fellows Committee Based on the principle 'if you can't get one, you need to make it yourself', the Provincial Fellows Committee decided to go into the training business; and thus the Provincial Core Training pathway was created.

As provincial specialists, we have a problem: we are getting older, fewer and wanting to slow down or stop practising. How can we find replacements willing to take on the rigours of provincial practice: the call, the relative isolation, the relative lack of resources, the difficulties of keeping up to date and the logistics of finding someone to cover for leave? Collectively, we had addressed some of these problems with initiatives such as SOLS (subsequently ROALS), but getting our city-trained and city-based colleagues to look over the mountains or along the coastline when seeking a position to practice wasn't happening, despite schools of rural health, compulsory rural rotation in training and some practice incentives. Was there another way?

The initiative

The idea of rural-based training came from the mind of A/Prof lan Pettigrew. He had undertaken the original negotiations with Training and Accreditation committee (TAC) to include a rural rotation in RANZCOG's ITP training. His first proposal was for a 12-month rotation, but the committee decided on six-month rotations. It was his belief that some provincial sites could be not only suitable for core training as a rotation, but also could act as the centre of an ITP.

The first Trainee's first year

Dr Robert North FRANZCOG Trainee

In late 2012, Prof Michael Permezel, who was then in the early days of his first term as President of the College, visited Dubbo to discuss with me, then the newly appointed Chair of the Provincial Fellows Committee, the possibility of establishing a rural training scheme. The day was spent discussing the various aspects of such a program and, following these talks, he suggested a representation be made to the RANZCOG Board on the matter.

After consideration of the issues and discussion with colleagues, a proposal for a provincially based training scheme was formulated. In essence, the primary site for training would be a large provincial centre with sufficient clinical activity, consultant presence, experience in registrar training and an association with a school of rural health to cover most of the essential components of training. Coupled with this would be an attachment to a tertiary centre to gain the specialised exposure that only these sites can now provide, especially in such areas as maternal-fetal medicine and oncology. It was clear that such a site could not reasonably accommodate a new Trainee each year and the solution to this was to partner with another provincial site with the capabilities as described. The two sites would preferably be close in distance and

My first year as the first RANZCOG Provincial Trainee is complete. How has it been? I have certainly enjoyed the work, I have learned a lot and I'm definitely a lot further ahead in the specialty than I was a year ago. My first year in Dubbo has also coincided with the opening of the new maternity unit. I don't remember the opening of the old unit. I was in Dubbo then, but only just, having been one of the last babies born in the unit before that one.

Having grown up and being educated here made it easy to come back and quickly settle in. Going back to being a junior registrar again has had its challenges, having been a VMO GP obstetrician and used to practising independently. This experience, however, certainly helped in this first year. I was used to acute medicine and clinical decision-making, so being the only doctor working in the labour ward needed only minor adjustment. The on-call consultant is not usually in the hospital, but has always been available when I've needed advice or assistance.

Initially, in doing procedural obstetrics, my confidence took a hit. I was critiqued and my bad habits were corrected. With practice, my skills and confidence quickly recovered and surpassed where I was when I started the year. That is exactly what I had hoped for. The overall experience has been positive. I have easily completed the requirements for the first year and made progress into the second-year assessments. I have been able to develop my research project and have it approved by College and the local HREC and have commenced data collection.

cooperate in the training of registrars at both sites. Having both sites in the same health district would also be helpful, especially for funding purposes.

The response from the RANZCOG Board was to recommend the establishment of a working party to look into this matter as well as other aspects of the rural obstetrics and gynaecology workforce. The working party was duly organised with the terms of reference along these lines. From an early meeting it was decided to progress the matter of a rural ITP by granting a pilot project to Dubbo Base Hospital (DBH).

The program

At the time of the proposal to go ahead with the pilot, DBH had been a rural training site for 16 years and was considered to have sufficient expertise in training, sufficient clinical activity and had been re-accredited for both Core and Advanced training for a further three years.

What was required was a program that maximised the training time at the primary site, in this case DBH, didn't dilute the workload (and hence clinical opportunities to any great degree), and which gave exposure to high-level services in a tertiary centre for a sufficient period during training. The program set out the first two training years at DBH rotating in the third year to Westmead Hospital (WMH) and finishing the fourth year back at DBH.

Another provincial site (Orange was the obvious choice) would take on a Trainee the next year of the program, following the same pattern. This would mean that there would be only one provincial ITP registrar rotating to WMH in any given year and that in the fourth year of training no WMH registrars would rotate to DBH, but could rotate to Orange. This allowed for a prolonged lag phase to be able to make adjustments to rural rotations for WMH registrars.

The preparation

Preparation for this pilot required the cooperation of a wide range of people and organisations. Firstly, the consultant staff at DBH needed to be comfortable taking on another Trainee, especially at such a formative stage of training. All agreed that the ultimate payoff would be worth the initial extra work involved.

Other associated craft groups, such as midwifes and paediatricians, were consulted and were agreeable to the plan. The hospital administration were also consulted and more than supportive of the proposal, especially as NSW Health and the health minister are both in favour of maximising rural training possibilities.

The specialists at Orange Base Hospital (OBH) were consulted regarding their willingness to partner with DBH in this venture and were enthusiastic in their support. As both hospitals are in the Western NSW Local Health District (LHD) administrative matters, such as funding, could be better coordinated. The CEO and Director of Medical Services were consulted and found to be supportive of the program.

Westmead Hospital in Sydney had been rotating registrars to DBH since 1997. They were approached through the training supervisor and head of department to be a part of the pilot. Some adjustments to their recruitment and rostering were required, but there was a willingness to be involved and when the final application for approval for the ITP was prepared for consideration by TAC, a comprehensive program and timetable were drawn up by them.

The selection process

What this training scheme needed in a Trainee was the commitment to rural practice. The attributes which were favoured in the selection process include having a rural background, being raised and educated in the country, having spent time in a rural centre as an

However, the department is far less busy than a tertiary hospital delivery suite. I believe that the level of experience gained from a ten-hour shift in a tertiary labour ward would require two or three days on call in a provincial hospital such as ours.

This situation aside, the other aspects of the job such as attending theatre, covering ED, performing ultrasound, antenatal clinic and studying, have all been satisfying. Learning is spread across the spectrum of our discipline, rather than concentrating on just one area at a time. This is what I expected and, because the pace of work is less hectic than a large unit, the role is less stressful.

The hours on duty and on call are longer in a provincial hospital, as the registrars rotated from the tertiary hospitals can attest to. We are rostered to a specific role each working day, with one day/night in three on call. On-call activity can vary from absolutely no calls to not getting to bed at all – both ends of the spectrum. Study time can be difficult to find, given the long on-call hours. While on call, study is often interrupted and on nights not on call sometimes sleep takes priority.

Having a third-year registrar rotate out from Westmead to our service is helpful for me in providing good peer support and an insight into the training program as it happens in a large metropolitan hospital. Otherwise, accessing peer review is difficult, making it hard for me to know how my progress compares to my fellow first-year Trainees. Perhaps teleconferencing with Westmead during registrar teaching sessions on a regular basis may help me get some perspective.

Most of my time this year has been spent training in obstetrics. Obviously, to have a registrar competent to manage the labour ward is the number-one priority. I am expecting that gynaecological training will take precedence in the second year. It is not that I haven't had any gynaecology experience this year as I've been able to do a number of laparoscopic salpingectomies for ectopic pregnancy, two vaginal hysterectomies and some other procedural gynaecology, which has given me a definite start.

Overall, I have enjoyed my first year on the training program. It has confirmed my decision to move from general practice to obstetrics and gynaecology. Obstetrics was my favourite part of general practice, hence the decision to make the change. Before starting the training in Dubbo, I was wondering if it would live up to expectations and be comparable to training received in a city hospital. I am sure a lot of other people wondered, and are still wondering, the same thing. So far so good.

undergraduate and hence somewhat familiar with rural life and practice, but most particularly someone who had postgraduate experience in a rural practice as a GP.

Applications were made through the usual College process, but with ancillary questions pertaining to the candidate's willingness to undertake rural training included in the application and those interested encouraged to apply.

In the first year (2014), the selection interviews were undertaken separately from the national selection process (several weeks before) and different interview questions used. There were 12 applications and five applicants were interviewed. Interviewees were given to understand that if offered the position, to decline would eliminate them from eligibility for an alternative position in the national allocation of posts, but those who were unsuccessful could still be interviewed in that process.

In 2015, the procedure was changed to have the interviews on the day of national interviews by the same panel, with two extra questions regarding rural practice. Unsuccessful candidates were ordered in the national ranking by their scores at interview, less the scores for the extra questions. This has streamlined the selection without compromising its intent.

The Trainee

The first Trainee on the program is Dr Robert North: he is likely to be the only future specialist obstetrician-gynaecologist to have been born in the old maternity unit at DBH. Robert was educated in Dubbo and is a graduate of Newcastle University medical school. He has a background in rural general practice. Robert was the after dinner speaker at the recent Provincial Fellows ASM, regaling us with his adventures climbing Everest and trekking through Antarctica.

The result

After the first year of the program, it is difficult to evaluate its success. However, the indications are positive. Robert has gained extensive clinical experience over the 12 months, easily comparable to metropolitan Trainees and, in some instances (such as operative gynaecology), possibly in excess of them.

The staff members within the maternity unit have recognised their increased obligations to the education of Trainees. Moreover, the



Dr Robert North, with the slopes of Everest in the background.

desire to be a training institute, in addition to a service provider, has been embraced.

Robert has had his research project protocol ('Predicting the time of onset of labour at term using fetal fibronectin') accepted by both College and the Western NSW LHD Human Research Ethics Committee. He was asked to develop a project the outcomes of which will provide major benefit to women in rural Australia, and he has done this. Data collection began in early 2016. He has been supported in this by the Dubbo School of Rural Health and they in turn have been enthused by the developing of a research culture within our department.

A Trainee was appointed to OBH for 2016. The consultant members of staff there are keen to develop a regionally based training schedule involving both Orange and Dubbo to enhance the training opportunities of all of our registrars using all the resources available to us.

There has been some interest from other rural centres in the program but to date, there have been no further applications to the College to be a provincial ITP site. Maybe they are waiting to see how we go in central western NSW. I hope they don't wait too long; there may not be too many trainers left if they do.



RANZCOG Women's Health Award winners 2015

Committed to promoting the specialty of obstetrics and gynaecology as an exciting and valuable career option, the College created the RANZCOG Women's Health Award award to help foster awareness of the specialty among medical students.

The College was proud to present the RANZCOG Women's Health Award 2015 to the following outstanding university students in obstetrics and gynaecology from medical schools across Australia, New Zealand and Papua New Guinea:

- Susannah McKinney, University of Auckland;
- Holly Powell, Australian National University;
- Alyce Scanlan, Bond University;
- Jonathon Schubert, Flinders University;
- Nicola Campbell and Ross Bourne, Griffith University;
- Deahnne Levas, James Cook University;
- Anastasia Phillipa Behan-Willett, University of Newcastle;



Dr Tania Widmer and Prof David Ellwood present the RANZCOG Women's Health Award to Nicola Campbell, Griffith University School of Medicine.

- Ronny Schneider, University of NSW;
- David Kerr, University of Notre Dame (Sydney);
- Meaghan Kelly, University of Otago;
- Susan Waiut and Inzaman Massat, University of Papua New Guinea;
- Albert He, University of Western Australia; and
- Eliza McDougall, University of Wollongong.



Dr Bernadette White presents awards to Dr Paul Mondia Jr (left) and Ms Tracey Jeff (right) from the University of Papua New Guinea.



Prof William Ledger presenting the certificate and cheque to Mr Ronny Schneider from the UNSW.



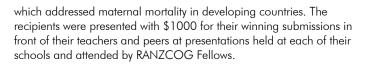
Writing award for secondary students continues to grow

Delwyn Lawson Coordinator, RANZCOG Foundation and Presidential Activities With this year's competition open for entrants, now is a good time to assess the success of the College's Liam and Frankie Davison Award for outstanding achievement in literary writing on an issue in women's health.

Applications opened on 31 January 2016 for the Liam and Frankie Davison Award for outstanding achievement in literary writing on an issue in women's health and, based on the response to the award in 2015, this year the field will be even more competitive than before.

In 2015, the number of entries for the award increased by 81 per cent from the previous year. Australian entries increased more than those from New Zealand, more than tripling from 2014 to 2015, with submissions received from Tasmania, ACT, New South Wales and Victoria. The judges were most impressed by the topics selected and the high quality of the entries. Both fiction and non-fiction pieces were submitted, covering a broad range of topics, ranging from anorexia, child marriage, pregnancy in the developing world and assisted reproductive technology to violence against women, sex trafficking, endometriosis, teenage pregnancy, stress urinary incontinence, maternal mortality, Indigenous women's health and HIV.

Coming in at the top of this competitive field with their exceptional submissions were Rachael Machado, of Whangarei Girls High School (Whangarei, New Zealand), who wrote about sex trafficking and sex tourism, and Izabella Watkins-Gray, of Hobart College (Hobart, Tasmania), for her powerful fictional piece called, 'A Girl of Iron',



Izabella Watkins-Gray first heard about the Liam and Frankie Davison Award from her English writing teacher, who encouraged her class to enter. A very passionate student, Izabella had previously taken a course examining women's health in developing countries. Although she found her research into fistula and other health issues that affect women in developing countries confronting, she was encouraged by the fact that she was helping to raise awareness of important women's health issues. Izabella was most appreciative for the award, she said, 'I'm so grateful to RANZCOG for running this competition, it's a wonderful opportunity for young people with an interest in either writing or women's health to explore and expand their understanding of both.'

Rachael Machado also found out about the award through an English teacher at her school, and wanted to enter because she felt



New Zealand winner Rachael Machado was presented with her award by Dr lan Page.



Dr Tania Hingston presented the Australian winner, Izabella Watkins-Gray, with her award.

she could contribute something meaningful. Rachael was inspired to write her essay after reading the book Slavery Inc: The Untold Story of International Sex Trafficking by Lydia Cacho and said she wanted her submission, 'to remind people above all: that becoming complacent, even ignorant, is the enemy of change'. Rachael found it a challenge to research and write about such an emotive issue: 'emotionally the process was difficult, I'm sure I cried more than once'. However, for those thinking of entering in 2016, her advice is: 'Go for it! It's not easy, but it's worth it, and regardless of the prize and prestige you will come out with a greater knowledge of the topic you chose and hopefully a greater passion for it.'

Applications for this year's award will close on 30 April 2016.

About the award

Open to students in their final three years of secondary school in Australia and New Zealand, the award was introduced in 2014 to increase awareness of the role and work of RANZCOG within the education sector below tertiary level. The name was changed from the RANZCOG Senior Secondary Students Women's Health Award to the Liam and Frankie Davison Award following the tragic loss of Liam Davison and his wife, Frankie, in the MH17 disaster. Liam Davison was a valued member of staff at RANZCOG, responsible for e-Learning, and Frankie a teacher at Toorak College for many years. The award was named in recognition of Liam and Frankie's shared passion for nurturing and encouraging young writers, teaching and good literature, and in the hope that this will be a meaningful legacy for Liam and Frankie. The award is intended to be of relevance not only to students intending to study medicine at tertiary level, but also those with an interest in a variety of subject areas from science and health, to law and politics. Further information is available on the RANZCOG website: www.ranzcog.edu.au/womens-health/students-women-s-health-award.html or by contacting: Mrs Anna Smaragdi, Administrative Officer – Meetings and CEO Activities t: +61 3 9412 2908, e: Ifdaward@ranzcog.edu.au .

Do you know that 20% of Australian women continue to drink alcohol after their pregnancy is confirmed? That's 1 in 5 women.

Australian women say they receive mixed messages about alcohol consumption during pregnancy.

When asked about drinking during pregnancy Australian obstetricians and gynaecologists have said:

"One glass of wine per day is ok" "One drink a day or five a week is acceptable..." "Don't drink daily, don't get drunk" "Alcohol is ok in moderation"

Are you adding to the confusion?

The 2009 National NHMRC Alcohol Guidelines state that for women who are pregnant or planning a pregnancy not drinking is the safest option.

Australian women trust their doctors, and having conversations about alcohol and pregnancy are welcomed and wanted.

The **Women Want to Know** campaign is supported by and developed in collaboration with the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, as well as other key health professional bodies and is funded by the Australian Government.

For more information regarding the FREE online accredited CPD courses, or to order free print resources, visit **alcohol.gov.au**.







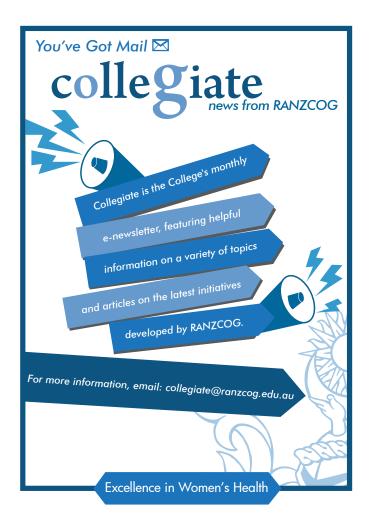
Australian Government
Department of Health

FRANZCOG logbook online

Kathryn Hertrick Coordinator, Quest

The College is currently implementing an important strategic initiative for the FRANZCOG Training Program by providing Trainees with an online portfolio.

Over the 2016 training year, the online portfolio will be implemented in stages. The first component of this program was the launch of the logbook for Trainees in New Zealand, on 14 December 2015, with Trainees in Australia following on 1 February 2016. At the time of writing, a total of 3500 procedures, clinics and scans had been logged from 87 locations, including Switzerland and the UK. The response thus far has been overwhelmingly positive. Dr Richard Pole, New Zealand Trainee Representative, said: 'I think it is great that we have an electronic logbook that can be accessed and updated from my iPhone. I am able to log my cases in a few seconds right after I do them –



potentially saving hours of admin time updating my logbook at the end of each semester.'

The logbook is accessible via mobile phones, tablets, laptops and desktop computers. It is essential all Trainees use the online logbook from the start of the 2016 training year, as the standardisation of data captured in the logbooks will enable the College to maintain standards and further enhance and the FRANZCOG training program. Features of the logbook include:

- predictive search for procedures;
- default hospital settings;
- automatic classification and tallying of entries;
- list tab to view all logbook entries; and
- the ability to update and delete entries via the list tab until they have been reviewed by the training supervisor.

Other components to be implemented over time include the Three-monthly Formative Appraisal for Semester One. Trainees will be able to initiate and submit appraisals online to their Supervisor for consideration. Then, when Trainees and Supervisors meet to finalise the appraisal, Supervisors will be able to record their comments online.



Dr Richard Pole sees the time-saving benefits of the online logbook.

Staff news



Left to right: Sanjeeva Padmaperuma, Pamela Hyde, Fiona Hopwood and Georgina Sack.

New appointments



Chelsea Miller started with the College in November 2015 as an Education Project Co-ordinator, working in the Education team. Her previous work experience is in secondary education, teaching English and History at Lalor Secondary College. During this time, Chelsea thoroughly enjoyed the dynamic and challenging pace of the classroom and working with young people. While on maternity/family leave in 2015, the role at RANZCOG presented a new opportunity to work in education.

Georgina Sack joined RANZCOG in January, as the Subspecialties Committee Coordinator, having previously temped at the College. Holding a BA and DipEd from LaTrobe University, Georgina has enjoyed a wide-ranging career, including teaching in Indonesia and a variety of roles in the health and education sectors.

Fiona Hopwood started at RANZCOG in January as an Examinations Administrator in Assessment Services. She brings to the role experience gained working for Pearson VUE, coordinating the worldwide exams for CPA. Fiona has a MA in Philanthropy and Social Investment, a postgraduate diploma in business and a BA, majoring in History and Dutch.

Pamela Hyde joined the College in December, as the Information Services Coordinator. She brings to the role experience gained working as a corporate librarian and business analyst leading information management remediation projects in the oil and gas and mining sectors. In her spare time she does volunteer work with UN Women Australia, World Vision and Starlight Foundation.

Sanjeeva Padmaperuma joined RANZCOG as an ICT Coordinator in January. He brings to the role extensive experience gained over 15 years in the ICT field, most recently working for the Administrative Appeals Tribunal and Whitehorse and Manningham Libraries. He holds a Bachelor in IT from Flinders University, South Australia.

Departures

Monica Yuill resigned from her role as an Examinations Administrator with Assessment Services in February.

Pippa Diggins resigned from her position as Examinations Administrator in February.

Grainne Murphy resigned from her position as RANZCOG's Museum Curator in January.

Mary Tsaousis resigned from her position as Subspecialities Services Coordinator in December 2015.

Georgia James resigned from her position as Global Health Coordinator, Global Health in December 2015.

James Leermakers resigned from his position as ICT Coordinator in December 2015.

Honours awards

The College congratulates the following RANZCOG Fellows and Diplomates, who recently received an Australia Day Honours award or New Year Honours award:

- Prof Lesley McCowan, for services to health, Companion of the New Zealand Order of Merit (CNZM).
- Dr Oswald Petrucco RFD, for significant service to medicine and education in the field of obstetrics, human reproduction and child health, and to professional groups, Member in the General Division of the Order of Australia (AM).
- Dr Peter William Ford, for significant service to medicine and to professional medical organisations, to healthcare delivery

for the aged and to the community, Member in the General Division of the Order of Australia (AM).

- A/Prof Edward (Ted) Weaver, for service to medicine and to medical education, Member of the Order of Australia in the General Division (OAM).
- A/Prof Rashmi Sharma, for service to medicine and to professional organisations, Member of the Order of Australia in the General Division (OAM).



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Obituary

Dr Roderick Donald Macdonald (1934 – 2015)

Roderick Donald Macdonald was born in Grafton on 1 October 1934 and died in Sydney on 16 May 2015. His former colleagues readily name him as one of the singular influences on their careers; he was an exceptional doctor and person, universally loved and admired by colleagues and patients alike.

Rod did his specialist training at Crown Street Women's Hospital, Sydney, and subsequently in London and Edinburgh in the UK. He returned in the mid-1960s to a consultant position back at Crown Street, which he greatly enjoyed, before choosing, in 1978, to become a foundation consultant at the new teaching hospital in the geographical centre of Sydney, Westmead, where he remained until his retirement in mid-1999.

Rod was a great practitioner of the art of obstetrics and gynaecology – highly skilled, knowledgeable and wise – but he was much more than that. He had no ego, nothing to prove. He never sought the limelight or his own advantage; never put his own interests ahead of anyone else's. He was uncritical, though not unobserving, and he treated everyone, patients and staff alike, in his characteristic unhurried and respectful manner. Patients waited months to see him, while GPs and registrars shamelessly jumped the queue for themselves or their families, eager to secure his precious attendance at the birth or surgery.

While he was mild and humble in his nature, he was quite bold in his clinical practice. He kept up to date and modified how he cared for patients whenever the evidence regarding best practice changed. He was an early proponent of keeping birth as natural as possible, employing dim lighting, early skin to skin time and encouraging the participation of the husband. Similarly, he was an early adopter of office hysteroscopy and cervical LLETZ/laser therapy to keep women out of hospital.

He was a wonderful colleague, his perfect blend of experience and humility making him highly sought after to discuss a tricky clinical scenario or share a less than optimal outcome. No matter the error a colleague might admit to, Rod would express support and sympathy – and then reliably trump it with a bigger mistake of his own.

He was an extremely energetic supporter of registrars, an enabling and forbearing teacher, always genuinely interested in the opinion of even the most junior trainee. He would listen attentively to the proposed management plan before agreeing 'yes, that's a good idea' as if, without the registrar, he wouldn't have thought of half of it himself. He also consciously took registrars through rare catastrophic scenarios they might encounter only once during their careers so if or when such an event did occur, they would be better prepared to manage it. He became a RANZCOG examiner to improve the registrars' pass rate, spending weekends marking tedious, meandering practice essays to broaden their knowledge and refine their technique until eventually, just in time, they were exam ready.

Finally, he had a great sense of humour, often expressed more in what he hinted at with a small smile than what he actually said. He was particularly famous for the creative ways he disguised his 'VIP' patients' names in the induction book.

Rod Macdonald was a wonderful doctor and an exceptional person. He leaves his gorgeous wife Robin, children Susan, Sarah, Angus and Hamish, thousands of patients and several generations of colleagues enormously thankful to have known him.

Dr Therese McGee FRANZCOG NSW

Notice of Deceased Fellows

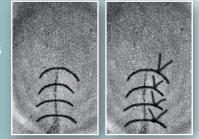
The College was saddened to learn of the death of the following RANZCOG Fellows:

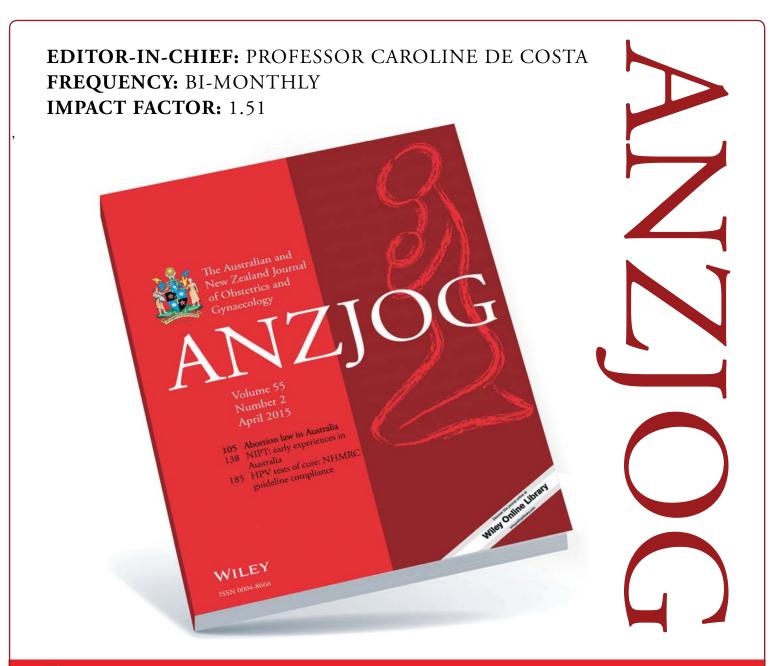
Dr William John Garrett, NSW, on 5 November 2015 Dr Charles Parr, New Zealand, on 4 January 2016



SURGICAL SKILLS COMPANION RESOURCES

The Surgical Skills Companion Resources is a suite of eLearning materials provided to support RANZCOG trainees. These resources will help to guide preparation for assessment of procedural and surgical skills during training.





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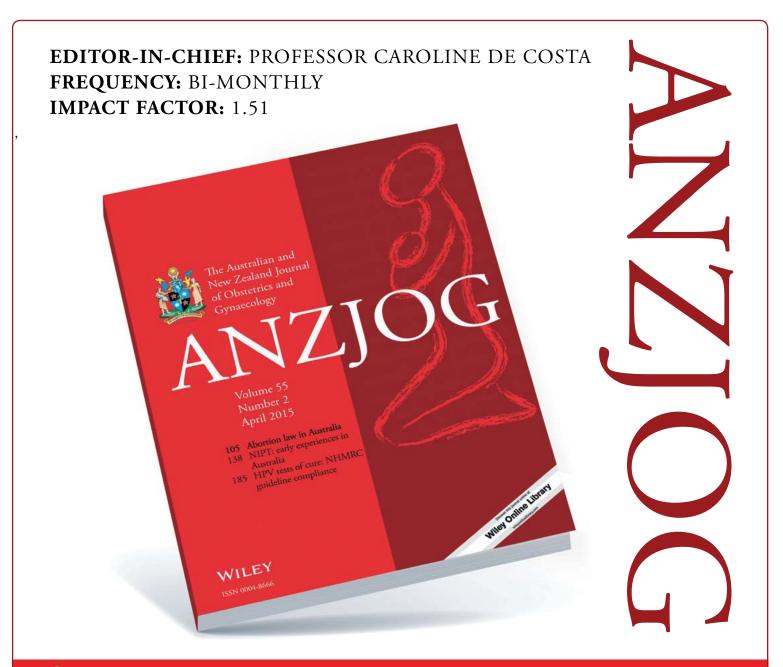
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