LETTERS

Oocyte cryopreservation as an adjunct to the assisted reproductive technologies

Keith L Harrison, Michelle T Lane, Jeremy C Osborn, Christine A Kirby, Regan Jeffrey, John H Esler and David Molloy

To the Editor: Cryopreservation has been an integral tool in the development of modern assisted reproductive technologies, beginning with sperm cryopreservation in 1953 and extending to embryo cryopreservation in 1983, with the evolution of in-vitro fertilisation (IVF) and embryo transfer as a major tool in the treatment of infertility.[1] Until recent times, however, there has been a lack of reliable cryopreservation methods for human oocytes. The world's first recorded pregnancy arising from frozen oocytes occurred in Australia in 1984,[2] and although occasional live births following oocyte cryopreservation were subsequently announced,[3] it was another 11 years before more reliable protocols were developed[4] — hundreds of live births have since been reported.[5] The most common protocol follows that of embryo cryopreservation, using slow freezing with propanediol as the cryoprotectant, although rapid vitrification methods are also being developed.

Reliable oocyte cryopreservation protocols are important for patients for whom embryo cryopreservation is unacceptable under some national laws or religions, and in whom there may be sperm collection problems or unexplained azoospermia during IVF procedures.

We report four live births, one ongoing pregnancy, and an ectopic pregnancy following oocyte cryopreservation. Three of these cases involved religious opposition to embryo freezing. In each case, only two oocytes were fertilised fresh and the remainder frozen. No pregnancies resulted from the fresh embryo transfers, and the frozen oocytes were subsequently thawed, fertilised, and transferred, to produce the pregnancies. Two cases involved idiopathic azoospermia on the day of IVF, while in another, no sperm could be obtained from testicular aspiration on the day. Oocytes from these men's partners were frozen until the sperm supply problems were resolved.

As these cases demonstrate, oocyte cryopreservation can serve as a valuable adjunct to assisted reproduction programs, by providing a solution to the occasional logistical problems caused by unavailable spermatozoa. It also provides another option for patients with ethical or religious objections to the cryopreservation of embryos, and for fertility preservation in women with cancer facing chemotherapy or for women who may wish to insure against age-related fertility decline.

The six pregnancies described here arose from embryo transfers in 13 women who had oocytes cryopreserved. The results, combined with others achieved worldwide, suggest that oocyte cryopreservation may at last be coming of age.

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Off-label use of medicines: consensus recommendations for evaluating appropriateness

Allen C Cheng, Priscilla M Robinson and Ken Harvey

To the Editor: We write in response to recently published consensus recommendations for the off-label use of pharmaceuticals, which provide a common-sense, evidence-based approach to a commonly encountered clinical problem.[1] The recommendations indicate that, other than for exceptional or research indications, off-label use of a medicine is generally not recommended unless there is high-quality evidence supporting such use. However, for some older pharmaceuticals, there is little incentive to perform additional trials to generate good evidence to support off-label use.

An example is rifampicin, which is commonly used in combination with fusidic acid to treat methicillin-resistant *Staphylococcus aureus* (MRSA) infection, but is not licensed or subsidised by the Pharmaceutical Benefits Scheme (PBS) for this indication. Rifampicin has a well defined toxicity profile, with a long history of use in treating tuberculosis and preventing meningococcal disease. Rifampicin-based combinations for staphylococcal infection are recommended by Australian and international guidelines,[2,3] and supported by small clinical trials.[4] For rifampicin, a generic drug, there is no financial incentive for the manufacturers to apply for an additional indication for treating MRSA infection.

Since 1998, an orphan drugs policy has encouraged sponsors of patented pharmaceuticals to apply for indications that may only involve small numbers of patients and has waived Therapeutic Goods Administration (TGA) fees for such marketing applications. A "rule of rescue" has also operated, lowering the regulatory bar for serious diseases that are otherwise untreatable. Despite these initiatives, no application to add the treatment of MRSA infection as an indication for rifampicin (in combination with another active agent) has been received by the TGA.[5]

A solution would be for the National Health and Medical Research Council (NHMRC) to commission clinical trials where further evidence is required. This proposal could see an expanded role for the National Institute of Clinical Studies (NICS), which will soon be incorporated into the NHMRC. The NICS/NHMRC could also make applications to the TGA for the approval of pharmaceuticals for particular indications, particularly for orphan diseases and generic drugs. Reviews of evidence could be generated from within the NHMRC or from external bodies such as professional Colleges and societies, or groups of experts such as those appointed by the Board of Therapeutic Guidelines Limited. Clinical trials could be performed in conjunction with overseas research agencies and draw from within the existing budget of the NHMRC.

This initiative would improve prescribing through the generation of appropriate evidence and may also redefine the utility of some established off-label indications. It could reduce out-of-pocket expenses for patients by facilitating PBS listing. As this initiative would focus on relatively low-cost generic drugs and/or uncommon orphan indications, it would be unlikely to have a significant impact on the cost of the PBS. It would also help focus the clinical

research agenda on clinical practice and encourage the use of appropriate generic pharmaceuticals.

Competing interests: Allen Cheng and Ken Harvey have been external drug evaluators for the Therapeutic Goods Administration.

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Addressing the health costs of the Iraq war: the role of health organisations

Luke Wolfenden and John Wiggers

To the Editor: The human costs of the war in Iraq are mounting. The war has already claimed the lives of about 3000 Coalition service men and women[1] and well over half a million Iraqi men, women and children.[2] Reports by the United Nations Assistance Mission for Iraq indicate that hundreds of thousands of civilians have been displaced, and that military operations in the country are limiting civilian access to health and education services, food, electricity and water supplies.[3] Furthermore, the reports describe a generalised breakdown of law and order in the country, continued growth of militias and organised gangs, and abhorrent human rights violations such as torture in the form of electrical and chemical burns, injury inflicted to eyes and genitals, and wounds from power drills and nails.[3]

Currently, the Iraqi health system is unable to cope with the health care needs of its population. Iraqi health infrastructure has not escaped the damage or destruction of war. Hospitals lack basic medical supplies such as intravenous fluids, antibiotics, oxygen, disinfectants and bed sheets.[4] The precarious security situation in the country has also contributed to a severe shortage of medical personnel. About 25% of Iraq's physicians have left since the beginning of the war, while those remaining are the targets of violence, intimidation and kidnappings.[4] Such an exodus of health personnel has required many of the remaining medical staff to undertake procedures for which they are not qualified.[4]

Recognising the need for action in Iraq, a workshop was arranged by the International Committee of the Faculty of Public Health, Royal Colleges of Physicians of the United Kingdom, in 2003. The workshop, which included representation from the World Health Organization and the Iraqi Ministry of Health, called for health organisations to be active advocates for improving the health of Iraqis and to provide technical support and assistance to their Iraqi health colleagues.[5] Training and professional development opportunities for health staff and the provision of up-to-date health information were identified as specific areas of need in the Iraqi health sector to which health organisations

could make a meaningful contribution. In Australia, there has been a small move in this direction, with the federal government providing in-principle support for an initiative to train three Iraqi physicians in emergency surgery.

Australian health associations, agencies and professionals need to do more to respond to the humanitarian crisis in Iraq. Carefully coordinated training programs, particularly in the areas of medicine and public health, and the provision of medical aid, resources and information by Australian health organisations, would enhance the capacity of the Iraqi health system to alleviate the effects of war on its citizens. Furthermore, health organisations and professionals need to advocate on behalf of Iraqis, raise awareness of the inadequacies of Coalition government aid, and demand a more effective humanitarian relief effort for victims of the 2003 invasion.

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Clinical paradigms revisited

Andrew P Wright

To the Editor: I was surprised by Wong's letter on the role of history-taking and examination in the diagnostic process.[1] I would suggest that Wong, as a surgical registrar, receives the majority of his abdominal pain referrals from the medical staff of the emergency department. Although he advocates the liberal use of abdominal computed tomography (CT) scanning, I believe he ignores the fact that another medical practitioner has already taken a history and performed an examination that has suggested a surgical cause of pain for which a surgical opinion is then requested. Wong would thus remain unaware of other cases in which patients present with abdominal pain but the case is ruled non-surgical on the basis of history, examination and limited investigation not involving abdominal CT scanning.

History, examination and even appropriately targeted investigations remain imperfect diagnostic tools, but I agree with Schattner[2] that history-taking and examination are very important adjuncts in the diagnostic process.

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Richard M Mendelson

To the Editor: Like Schattner, I am appalled by the attitude to diagnosis displayed by Wong regarding the use of computed tomography (CT) scanning in

preference to initial history-taking and physical examination in abdominal pain.[1] Unfortunately, this approach is becoming increasingly more prevalent among junior staff (and even among some senior staff).

Wong poses the question, "[W]hy do some clinicians continue to routinely promulgate the sacred and arcane ritual of taking a history and doing an examination, which, as diagnostic tools, are clearly second-rate?" There are several reasons why I continue to promulgate the classical paradigm.

Firstly, I would remind him of Bayes' theorem: post-test probability equals pre-test probability multiplied by the likelihood ratio of the test. Put simply, this means that, for a test that is not 100% accurate (ie, effectively, all imaging tests), you cannot interpret the meaning of the result without having some idea of the pre-test probability of a diagnosis. And how can you satisfactorily arrive at a pre-test probability without having clinically assessed the patient? In addition, the radiologist is able to interpret the images more accurately when there are clinical details provided.[2]

Secondly, is Wong seriously suggesting that all patients with abdominal pain, including young adults and children, undergo CT scanning without any kind of clinical filtering or assessment? This is wrong and potentially negligent. The radiation dose received by the patient from an abdominal CT scan is a serious consideration. Assuming a total effective body dose of 10 mSv, there is an excess risk of a radiation-induced fatal cancer of about 1 in 2000.[3] Apart from the risk to the individual, the number of iatrogenic cancers potentially induced in the community by indiscriminate use of CT would be a major concern.[4]

Thirdly, the implication of Wong's letter is that clinical assessment and imaging are somehow in competition with each other, whereas nothing could be further from the truth. Of course, modern imaging has contributed to making diagnosis far more accurate than in the time of Hippocrates, but a complementary approach is far more rewarding for patients and doctors.

Lastly, in patients with abdominal pain, there are many occasions when no imaging is required and others when ultrasonography is more appropriate than CT, because it avoids ionising radiation in young patients and is more accurate for diagnosing gynaecological causes of pain.[5]

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James L Mallows

To the Editor: It is clear Dr Wong[1] has a practice rather different from mine. He is not used to the truly undifferentiated patients that present in their thousands to emergency departments and general practices every day. There, the art of history and examination is truly alive.

No one questions the value of complex imaging. It has its place after a detailed history has been taken and focused examination and relevant investigations have been carried out, leading to a risk assessment and management plan. One does not order computed tomography (CT) scans willy-nilly. For example, the Canadian CT Head Rule[2] for patients with minor head injury sets out which patients should have a head CT scan, based on a simple set of historical and examination findings. Moreover, CT scans are wasted on conditions for which CT imaging is inappropriate — it is rare that I order a CT scan for a child with abdominal pain.

When I ask surgical registrars for their opinion, I am actually asking for their consultant's opinion. Nothing guides like an experienced hand, whether it be feeling a belly or writing a CT request form. On many occasions, I have concluded that all the imaging performed on a patient with abdominal pain did not contribute to the diagnosis and the patient simply needed a laparotomy. At my insistence, the consultant is called, appropriate treatment commences, and the patient boards the experience express on the track to recovery. As Shem quips, in his satirical book on medical training and hospital life — nothing heals like cold steel.[3]

CT is not the be-all and end-all of medicine. Hopefully, by the end of his training, Wong will have developed the hand of experience and be able to continue the art of medicine through the ages. In the words of William Osler:

> The practice of medicine is an art, not a trade; a calling, not a business; a calling in which your heart will be exercised equally with your head. Often the best part of your work will have nothing to do with potions and powders, but with the exercise of an influence of the strong upon the weak, of the righteous upon the wicked, of the wise upon the foolish.[4]

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Sandeep Chauhan, Ruth D'Cruz, Sanjay D'Cruz, Ram Singh and Atul Sachdev

To the Editor: Apropos the letter by Wong entitled "Clinical paradigms revisited" in the Christmas issue,[1] declaring fossilisation of the very pillars on which medicine stands, we would like to express a contrary opinion.

To be adept physicians, clinicians must hone their skills at taking a lucid and informative history and conducting a thorough physical examination. It would be a crying shame if young doctors, having slaved for 5 or more years to obtain a medical degree, had to rely solely on expensive investigations when they have the God-given tools of the five senses. To confirm a clinical diagnosis and assess the extent of disease, doctors should order specific and appropriate investigations, rather than ordering tests that may be irrelevant and financially bleeding the patient. The issues of cost, radiation hazard, availability of trained personnel, and need for expensive equipment have been trivialised.

In a country like India, where the majority of the population cannot afford even minimal hospital fees, to even contemplate using a computed tomography scan as a

first-line diagnostic tool for something as basic as abdominal pain is absurd.

Moreover, the use of advanced technology does not guarantee a correct diagnosis. A recent case of aortic dissection was misdiagnosed as acute coronary syndrome on the basis of electrocardiography.[2] If due emphasis had been given to pulse and blood pressures in both limbs, this mistake could have been avoided. In another case, involving recurrent loss of consciousness, investigations were non-contributory, but a history of substance misuse at home pointed to the correct diagnosis.[3] In another study, clinical judgement regarding the severity of pneumonia was found to be a more reliable predictor than a standardised scoring system based on clinical signs and laboratory findings.[4]

Doctors ought to be able to make a clinical judgement in the first instance, rather than resorting blindly to expensive investigatory tools. We do not deny the usefulness of modern technological devices for confirming or ruling out clinical possibilities, but they must be used judiciously. Such investigations cannot take precedence over physicians' reliance on their clinical skills, lest we become helpless without technology.

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Stuart Kostalas

To the Editor: Schattner[1,2] and Wong[3] raise issues that examine what has been the core of medical practice since antiquity. Grasping antiquity for its own sake is problematic, at best, and possibly heralds the extinction of long held practices, at worst. As technology improves, we are witnesses to improved imaging modalities that provide higher diagnostic yields, with improved sensitivity and specificity, at increasingly reduced costs. Refusal to even acknowledge the possibility that the history and examination may be terminal is not prudent. Instead, we need to examine carefully our mantra(s) with respect for the temporal nature of medicine.

History and examination evolved in their current form *because* previous generations could not see inside the body, or examine physiological and pathological processes in real time. Our predecessors amassed a series of verbal cues and physical rules that *generally conformed* to the presentation of a particular disease. The future of medicine heralds dramatic departure from the world view that preceded computed tomography and magnetic resonance imaging.

Wong raises an important issue with regard to diagnosing emergency abdominal conditions in busy hospital practice. He does not discount a role for the history or physical examination. He does, however, challenge their pre-eminence in "conditions that require emergency surgical treatment". Is it really in the best interests of patients and the health care system for the emergency department intern/resident, then the registrar/consultant, then the surgical fellow, to all take the history and perform a physical examination? In essence, doesn't Wong's "scan first approach" reflect a prudent reliance on, and respect for, the information already gathered?

Schattner[4] states that "all imaging studies combined (computed tomography, magnetic resonance imaging, ultrasound, and echocardiography) were decisive in only 10.5% of cases" whereas "the patient's history and the evolution of the condition proved to be the decisive diagnostic method in 23% of cases". Doesn't this show that Wong's approach provides a heuristic that increases the diagnostic yield, reduces delays and guesswork, and streamlines the processing of patients presenting with acute abdominal pain — or is it acceptable to miss the significant percentage of diagnoses that are decided by imaging alone?!

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The absence of many voices in protest

Michael J Cousins

To the Editor: In his message *From the Editor's Desk*,[1] Van Der Weyden laments what he perceives to be "the absence of many voices in protest" against the current Council of Australian Governments' (COAG) proposals[2] for national systems of registration and accreditation of the Australian health workforce.

The absence of an "overwhelming public response" to the proposals can surely be attributed to the general public's lack of awareness of the proposals. It cannot be said, however, that the medical profession has been idle.

By the time this letter is published, the situation in regard to the proposals is likely to be much clearer. To date, all elements of the medical profession have been very active in seeking to achieve the best possible outcomes from the COAG proposals for our patients and for the profession. These efforts were impeded initially by the lack of specificity available from the COAG Health Working Group.

Clear evidence of the effectiveness of the efforts of the Australian Medical Council, the Australian Medical Association, and the Committee of Presidents of Medical Colleges (CPMC) (http://www.cpmc.edu.au) and its individual member Colleges was the abandonment of the second consultation paper after the profession's analysis and evaluation of the proposals presented. As I write, government officials are meeting to develop a new model which recognises the profession's criticisms and views.

The profession's message clearly has reached the federal Minister for Health, who asserted recently that it appeared that "the best way forward is to have separate national registration boards for medicine and for each of the other health professions".[3] This is a significant departure from the original COAG proposal.

The CPMC and its member Colleges are well aware of the undesirable developments in other countries where governments are attempting to take control of regulation of the medical profession, as mentioned by Van Der Weyden.[1] At their meeting on 15 February, the College presidents endorsed a two-page statement of key issues in regard to the COAG proposals. This statement has been sent to the premiers, chief ministers and health ministers in each state and territory,

as well as to the relevant federal government agencies.

At the same time, it is appropriate for the Colleges to cooperate responsibly with government initiatives, provided those initiatives do not diminish in any way the safety and quality of health services provided in Australia or threaten the sovereignty of the Colleges in the determination and maintenance of standards for their respective disciplines.

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Derek H Meyers

To the Editor: Your statement that the present "grab for control [of Australian medicine] by governments" is unprecedented is not correct.[1]

Between 1946 and 1949, the federal government came close to nationalising the medical profession.[2] The lines were drawn earlier. In 1941, the Federal Council of the British Medical Association (BMA) in Australia (now the Australian Medical Association) made recommendations about the provision of medical services. Two years later, in response to a report by the National Health and Medical Research Council, *Outline of a possible scheme for a salaried medical service*, the BMA laid down a more detailed policy, with retention of the existing (largely private) general practitioner and specialist services. The government responded by proposing a scheme under which patients would pay nothing directly for medical care, with costs to be met from general revenue.[3] Asking the doctors to cooperate, the government indicated that it would if necessary seek other means to achieve its object.[4]

The referendum of 1946, one of the few to be passed, gave the federal government power to provide a range of social services, including pharmaceutical and hospital benefits and medical and dental services. There were, however, a few words of critical importance in the question put to the people — "but not so as to authorise any form of civil conscription". It was the Leader of the Opposition, Mr (later Sir) Robert Menzies (acting on a request from Sir Henry Newland, President of the BMA Federal Council and a surgeon of great distinction), who moved the amendment, which the government accepted.

The referendum enabled the government in 1948 to pass the *National Health Service Act 1948–49* (Cwlth). Resistance by the BMA to what it regarded as objectionable features led to an attempt to coerce the profession by enforcing the *Pharmaceutical Benefits Act 1947* (Cwlth), which required compulsory use of a Formulary issued to all doctors. (In the event, only 2% of doctors ever used it.) The BMA took the issue to the High Court of Australia, which decided in August 1949 that a section of the Act amounted to civil conscription and was invalid. Later in the year, the heavy defeat of the government, the result of its attempt to nationalise the banks, sealed the doctors' victory.[5]

Over the next few years, the coalition led by Menzies introduced a health service based on the principle of voluntary insurance for hospital and medical benefits, which is still in force.

There are clear lessons to be learned from this history.

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