SENSE, SENSIBILITY AND OLDER PEOPLE

Communication is at the centre of effective health care — and yet this critical dialogue can be problematic, especially when trying to forge links between the languages of two disparate worlds: society and medicine.

Medicine has a distinct language, which enables doctors to communicate among themselves with relative ease. To participate within this framework, medical students must learn a second language, and on graduating they will have amassed some 55,000 new words upon which to draw.

Despite its professional utility, “doctor speak” also involves the use of jargon, which instantly captures clinical circumstances but can be insensitive and even alienating. Examples include the use of crinklies and crumblies for older patients, dementes for patients with dementia, and bedblockers for older patients in acute hospitals awaiting placement in nursing homes; and there are more.

It is interesting to note that this dehumanising language is mostly used for older people; some argue that this reflects their vulnerability and loss of power. But a backlash is now underway.

A recent Europe-wide survey of older people revealed a strong preference for the use of older or senior in describing themselves. Terms such as elderly, aged and even old were found to be unwelcome and unacceptable. Elderly, in particular, provoked immediate censure. Such sentiments are in line with the deliberations of the United Nations Commission on Human Rights.

Despite this finding, the public media, medical bodies, and journals persist in the use of elderly, with its implicit connotations of functional decline, frailty, disability, and being a burden on families and society. The term elderly effectively ignores the positive aspects of older people, such as their experience, wisdom, creativity and emotional resilience.

Perhaps we should all be attuned to the sense and sensitivity of the language we use — for none of us are immune from growing older.

Martin B Van Der Weyden
Potential impact of AUSFTA on Australia’s blood supply
Glen A Kennedy, Judy Cummings and Simon T Durrant

To the Editor: We read with great interest the article by Bambrick et al relating to the potential impact of the Australia–United States Free Trade Agreement (AUSFTA) on supply of blood products in Australia.1 Our recent experience with Octagam (Octapharma Australia, Sydney, NSW), an intravenous immunoglobulin (IVIg) product produced overseas, highlights some of the quality concerns raised in their article.

Routine practice in our bone marrow transplant unit is to administer IVIg weekly for 100 days after allogeneic stem cell transplantation. Until December 2004, locally produced IVIg, Intragam-P (CSL, Melbourne, Vic), was used exclusively as the IVIg product for these patients. From October 2005, because of limitations in the supply of Intragam-P, the Australian Red Cross Blood Service (ARCBS) also provided Octagam for IVIg replacement therapy in transplant recipients.

It has also been routine practice within our transplant unit to repeat serological tests for a variety of transfusion-transmitted viral infections, including human T-lymphotropic virus type I and type II (HTLV-I and HTLV-II), in all transplant patients 100 days after transplantation. Until 2006, none of our patients had ever tested positive for HTLV-I or HTLV-II antibodies. After the introduction of Octagam, the first two transplant patients who received this product for IVIg replacement tested positive for HTLV-I/HTLV-II antibodies at 100 days after transplantation (signal to cut-off S/CO ratios, 4.36 and 6.33, respectively).

Subsequent investigation revealed that these results were probably secondary to passive transfer of HTLV antibodies from the IVIg product used. Both patients received Octagam from the same batch, and subsequent testing of this batch was positive for the presence of HTLV-I/HTLV-II antibodies. Of note, both patients tested negative for HTLV-I/HTLV-II antibodies before transplantation (S/CO ratio < 1.00). Their stem cell donors were also negative for HTLV on testing immediately before stem cell donation, and the only other blood product shared between the two patients (platelets from a common donor) also tested negative for HTLV. Follow-up testing for HTLV-I/HTLV-II antibodies at about 12 months after transplantation gave a negative result in both patients (S/CO ratio < 1.00).

Given that Octagam is a plasma (acellular) product processed with appropriate viral inactivation steps,2 we believed it to be extremely unlikely that direct transfer of HTLV virus had occurred. The most likely explanation was the passive transfer of HTLV antibodies. It followed that Octagam must have been sourced from HTLV-positive plasma donors — a practice that is in direct conflict with current ARCBS policy, which specifies that all blood and plasma donors must be screened for HTLV-I and HTLV-II, and that any donors testing positive should be excluded from blood or plasma donation.3 The HTLV-I/HTLV-II serostatus of donors used to source plasma for Octagam is not reported on the product information sheet.2 Testing of one patient sample at the National Serology Reference Laboratory (Melbourne, Vic) suggested the positive serological results in our patients were due to the presence of HTLV-II antibodies. In collaboration with Octapharma, it was subsequently determined that plasma for Octagam was sourced from paid donors from the southern United States, an area where HTLV-I and HTLV-II seropositivity is known to be prevalent among blood donors.4

The clinical implications of our findings are unclear. Our results were reported rapidly to the ARCBS and subsequently to the Therapeutic Goods Administration. Our main concerns are that Octagam plasma is sourced from donors who would normally be excluded from plasma donation within Australia,3 and that there appears to be no current mechanism for addressing this issue. Some of the quality concerns raised by Bambrick et al appear to be not so theoretical after all.

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In reply: I would like to respond to the letter by Kennedy et al regarding the passive transfer of human T-lymphotropic virus (HTLV) antibodies following Octagam (intravenous immunoglobulin [IVIg]) administration.

Octapharma does not routinely test Octagam for HTLV antibodies — this is in line with Australian regulatory requirements.1 Furthermore, in accordance with global regulatory requirements (including those defined by the Australian Therapeutic Goods Administration), plasma from sources in Europe and the United States is also not routinely tested for HTLV antibodies.2,3 It is important to note that the patients described by Kennedy et al tested positive for HTLV antibodies rather than the HTLV virus, and that the presence of antibodies in the finished product does not pose an infection risk.

As noted by the authors, the manufacturing process for Octagam includes viral inactivation. There are two dedicated viral inactivation and removal steps:

- Solvent/detergent treatment, which is a highly effective step for inactivating lipid-enveloped viruses;
- Incubation at pH4 and 37°C for 24 hours.

The combination of these two processes ensures that lipid-enveloped and several non-lipid-enveloped viruses are inactivated. Since the initial launch of Octagam in Europe in 1993, more than 33 million grams of the product have been infused, corresponding to more than 2.5 million infusions. During this time, there have been no documented cases of viral transmission resulting from the use of Octagam.

Since the launch of Octagam in Australia in 2005, Octapharma has supplied over 600 kg of IVIg, representing about 40 000 infusions to Australian patients.

Therefore, taking into account the steps used to remove and/or inactivate lipid- and non-lipid-enveloped viruses, the fact that there have been no documented cases of transmission of any virus since the launch of Octagam, and that plasma sources and testing meet both Australian and global regulatory requirements, the positive HTLV antibody results reported by Kennedy et al have no bearing on either the quality or safety of Octagam.

Competing interests: Octapharma is the manufacturer of Octagam. I am employed by Octapharma in the role of International Medical Director.

Wolfgang Frenzel

LETTERS

3 Australian Red Cross Blood Service. Transfusion medicine manual. Chapter 3. Collection and prepa-
Alison Turner and Albert Farrugia

TO THE EDITOR: Bambrick et al suggest that the importation of overseas plasma products or the processing of Australian plasma overseas may pose a threat to the safety and security of Australia’s supply of plasma products. The National Blood Authority (NBA) and the Therapeutic Goods Administration (TGA) would like to respond to these issues to ensure that clinicians have confidence in the safety of products currently available in Australia and a better understanding of current blood processing and supply arrangements.

Australia is largely self-sufficient in plasma products, a position supported by all Australian governments. The governments also agree to the supply arrangements for imported plasma products when demand exceeds domestic supply (as in the case of intravenous immunoglobulin [IVIg]), and for products not supplied by Australian manufacturers (eg, fibrin sealant and other coagulation products). All these products are purchased by the NBA on behalf of Australian governments. Standards applied in Australia ensure that all products on the Australian market are derived from sources in Europe, the United States and Australia — approved by the relevant authorities. The TGA regulates all plasma products to ensure that they meet international standards of safety, quality and efficacy, irrespective of their source.

National health systems around the world strive to attain degrees of self-sufficiency that suit their particular economic and policy objectives. However, as the US supplies 60%-70% of global plasma (while consuming only 40% of products sourced from this plasma), many patients outside the US are dependent on the system of both compensated and uncompensated donors operating in the US. It is worth noting that definitions of “remuneration” vary across countries. The Commission of the European Communities reported in 2006 that “the principle of voluntary and unpaid donations does not exclude compensation for donors, if it is limited to making good the expenses and inconveniences related to the donation.” Examples of compensation that this article cites include tax relief of up to €70 per annum in the Czech Republic, an expense allowance of up to €25 for a whole blood donation in Germany, and up to €50 for an apheresis donation in Austria. Thus, the boundary between compensated and non-compensated donors is not distinct globally.
Bambrick and colleagues’ contention that products manufactured from paid donors may be less safe is not supported by evidence. The history of blood safety clearly demonstrates that there were major safety issues with both fresh blood and blood products in the 1980s. These problems were more a result of pathogen epidemiology and governments’ blood safety policies than whether donors were paid or unpaid. For example, the Canadian and French blood systems relied entirely on volunteer donors, but the delayed implementation of safety measures and good governance measures led to pathogen risks that exceeded those of the US.6,7 In Australia, the incidence of HIV/AIDS in people with haemophilia exposed to only one type of product in the 1980s approached that of the same patient group in the US, despite the product being sourced entirely from domestic voluntary donors.8

Currently, robust plasma product safety measures in the US have proved to be effective in minimising contamination from both known and emerging pathogens, such as West Nile virus. This virus did not infect the recipients of plasma products from compensated donors, but did infect the recipients of (uncompensated) fresh blood transfusions.9 The equivalence in safety between plasma products sourced from compensated and uncompensated donors has been confirmed by the European Medicines Agency.10

Ensuring the security of supply is central to Australia’s plasma fractionation arrangements. The NBA’s contracts include provisions to ensure product supply security and product safety, including compliance with TGA requirements. Under Australia’s emergency response plans, plasma could be supplied from fresh stock, while the inventory of product in the system and the national reserve of products (funded by the NBA to cover contingencies) could provide fractionated products. A range of other supply security measures is implemented by the NBA on behalf of Australian governments, including secondary suppliers for critical products. These measures take into account the fact that Australian plasma used to manufacture fractionated products is not produced in sufficient quantities to permit storage of excess. Thus, Bambrick and colleagues’ concern that geographical factors may restrict access to Australian plasma has limited relevance in an emergency situation.

In summary, Australia has a comprehensive system that draws on international best practice and national jurisdictional arrangements to ensure the supply of high-quality, safe, efficacious plasma products, irrespective of their source.

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Hilary J Bambrick and Thomas A Faunce

In reply: Turner and Farrugia highlight important issues about the safety and supply of Australia’s blood and plasma that constituted key findings of the recent Australian Government review of Australia’s plasma fractionation arrangements. These included the desirability of self-sufficiency and the need for a viable contingency plan in the event of local supply failing to meet demand, in the context of probable increased uncertainty in relevant security and supply circumstances.

The authors note the importance of a rapid regulatory response to new risks, and rightly emphasise the important role of our National Blood Authority and the Therapeutic Goods Administration in relevant safety assurance processes. However, a crucial issue highlighted in the review that they fail to address is the difficulty of relying on the application and enforcement of regulatory standards if the bulk of Australia’s fractionation occurs offshore.

After an exhaustive study of arrangements in Europe and the United States, the review concluded that overseas fractionation of Australian plasma would involve significant costs in moving away from the current local arrangements ($75 million) and, because of yield considerations, there would be the potential for an ongoing shortfall in the supply of intravenous immunoglobulin (IVIg) and other plasma-derived products. The review also found that overseas fractionation was potentially associated with major risks to the supply chain, with increased distance and handling providing more opportunities for loss and error, while a doubling or tripling of the turnaround period would have implications for continuity of supply. The review recommended that the federal government maintain the reservation exempting plasma fractionation services from the government procurement provisions of Chapter 15 of the Australia–United States Free Trade Agreement.

The review confirmed that volunteering for blood donation should be institutionally reinforced as an important exemplar and means of sustaining Australia’s national culture, and that donor payment endorsed a very different set of values and was unlikely to assure sustainability of supply. It did, however, suggest initiatives such as tax relief or other institutional ways to encourage donation.

We fully endorse the summary assessment of the review that:

[The current structural arrangements, whereby domestically collected plasma is fractionated by CSL Bioplasma, are subject to careful monitoring of prices, in Australia’s best interests. The present system is well entrenched in the “hearts and minds” of the Australian population and of the Australian medical community and, particularly, in the strategy, thinking and reliance of all end user groups.]

Competing interests: Hilary Bambrick is related to Philip Flood, Chairman of the Plasma Fractionation Review Committee. He has had no input into this letter. Thomas Faunce is Project Director of an Australian Research Council (ARC) grant investigating the impact of international trade agreements on Australian medicines policy. The ARC was not consulted about the preparation of this letter.

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Prevocational medical training and the Australian Curriculum Framework for Junior Doctors: a junior doctor perspective

Lilon G Bandler

To the Editor: Gleason et al describe the continued tendency of hospitals to allow prevocational, newly graduated doctors to flounder as they provide the cannon fodder to keep those hospitals running.

For about 5 years, I coordinated an education program for junior medical staff. It is a model that other areas could consider. The

430 MJA • Volume 186 Number 8 • 16 April 2007
Northern Sydney Area Health Service — as it was then — had two primary allocation centres for junior staff, and three local secondment hospitals. During their time in Sydney, all interns at those five hospitals were required to attend a 3-hour program of education provided for them, off site, each fortnight. In the first week, half of the interns attended; the program was repeated the following week to allow the other half to attend. A separate program was developed for Postgraduate Year 2 doctors that provided day-long programs centred on a particular topic (eg, renal disease or paediatrics). Each hospital put half of their Postgraduate Medical Council of New South Wales (now NSW Institute of Medical Education and Training) funding towards the cost.

The teaching was provided by clinical staff within the area health service. The size of the area health service meant that there was an enormous pool of expertise to call on. The very size of that pool meant that we did not over-use the same keen teachers. The quality of the teaching was regularly rated as high by the doctors who attended. The off-site venue meant that time was truly quarantined. The provision of breakfast and morning tea meant an opportunity for junior medical staff to spend time with their cohort, compare experiences, complain, commiserate, and congratulate, in an informal atmosphere.

Of course senior staff — administrative and medical — would complain. However, they gradually grew used to the format, and learned to time rounds, to make allowances and to value their happier, better educated and medical — would complain. However, they gradually grew used to the format, and

Hospitals must meet their training responsibilities and should not continue to place service demands above the training needs of doctors. Teaching time needs to be a regular, protected, paid part of every junior doctor’s day.

In 2007, it is completely unacceptable to continue to see junior medical staff as “workforce”. It shames us all as senior physicians that we have not ensured that all hospitals meet their educational and training responsibilities to these valuable members of our profession.

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Medical education registrars: new thoughts on old problems
Andrew M Foote

TO THE EDITOR: Medical education faces a number of significant challenges in the coming years. The most concerning problem is that there are insufficient medical educators. To compound this problem further, clinicians with an interest in teaching lack academic recognition, funding, time for medical education, and institutional support.

While this is already creating problems for training of medical students and junior doctors, the situation will only become worse as the number of graduates increases to meet workforce shortages. A greater number of medical students and graduates will put further pressure on an already over-stretched health system to deliver adequate medical education. Therefore, we need to consider new ways of creating effective clinical teachers and learning materials that are educationally sound and supported by research.

One way to address some of these deficits is to create specific training positions for doctors interested in pursuing a career in medical education, perhaps called “medical education registrars”. These positions could be jointly funded by hospital networks, universities and other interested groups, such as the postgraduate medical councils, and could be aimed at doctors with a strong interest in medical education, especially those at an early stage in their career, such as postgraduate year (PGY) 3 and PGY4. This joint funding would support hospitals and universities working collaboratively, and taking responsibility for making medical education “a priority, rather than an add-on”. The hospital appointment would maintain the registrars' clinical knowledge, and the university appointment would allow opportunities for further study in medical education theory and research methods. Both environments would allow for academic mentoring.

These registrars would then be ideally placed to assist in the development, implementation and evaluation of education materials using the newly released Australian Curriculum Framework for Junior Doctors as a guide. While agreeing that the Framework provides a “unique opportunity to improve the quality of medical training in Australia”, Gleason et al expressed concerns about how the Framework would be implemented. Medical education registrars could play a pivotal role in this process, and would be strong advocates for junior doctors.

Medical education registrar positions are a simple, cost-effective way to encourage clinicians, especially those early in their careers, to pursue medical education as a serious and satisfying career path. Urgent action is required now to avert certain disasters in a few years, when hospitals are full of medical students and junior doctors, and there is no one to supervise and train them.

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LETTERS
Fiona R Lake

IN REPLY: A teaching registrar position is a great idea. It could foster development of knowledge and skills in interested clinicians, and perhaps higher degrees in learning and teaching, as well as serving as the start of a career pathway. The United Kingdom allows specialist trainees to take a year out to develop skills in education or research. Here, however, it is doomed to fail, unless there is a receptive environment for these registrars to work in or a career path that is attractive.

What kind of educational environment is needed? We need leaders with vision, knowledge, new ideas and resources to lead the development of programs and assessment. We need teachers whose main focus is to teach and implement programs. And we need to support all clinicians to continue to supervise and teach. Not all these roles need to be performed by a medical practitioner.

Without all of this, someone who is “interested in teaching” may be burdened with an unsustainable level of teaching and administration.

Better integration at a local level across undergraduate and prevocational training (not to mention linking with other professional groups) and a culture of teaching are needed. Importantly, we need coherent and visionary leadership at national and state levels to underpin these endeavours.

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