EDITORIAL / VAN DIE REDAKSIE

MASA — actions louder than words

The *SAMJ* has frequently been the recipient of correspondence and telephone calls from irate members wanting to know what the Association is doing about a variety of issues that are of fundamental concern to the profession — concerns that have often generated vigorous correspondence in our 'Letters' section. The *SAMJ* has therefore deemed it appropriate to look into the position of the Association in respect of these issues, and to provide its readers with up-to-date information on them.

One such concern has centred around the absence of an appeals procedure against SAMDC disciplinary committee hearings. The MASA has pursued this matter with the SAMDC over the years, and was recently able finally to reach agreement with the Council on the need for the right of appeal to the Supreme Court on the substance (rather than just the procedure) of the hearing and the verdict. This agreement, which represents a major breakthrough for the profession, must now be taken further through the channels necessary to convert it into legislation.

Secondly, the MASA has successfully negotiated an above average increase in the rates of RAMS Scale of Benefits for 1994, and has further won the retention of direct payment of medical aid claims to the doctor, all of which represent the benefits of the recently established formal negotiation agreement between the MASA and RAMS. RAMS has further agreed to grant an additional rate increase in about 6 months, provided that the doctors achieve savings for the societies through the containment of prescription and hospitalisation costs. Although it bears repeating that the doctor is not the sole or even the main cause of the high cost of medical care, there is no doubt that both these areas present good opportunities for cost-containment without threatening the quality of care offered to the patient, and the offer of incentives by RAMS represents a sensible way of addressing the escalation of health care costs in South Africa.

Thirdly, the government has come up with additional funds earmarked for certain 'disadvantaged' categories in the public service. The MASA has lobbied strenuously for a sizeable portion of those funds to be allocated to the hard-pressed doctors in state employment, for it is well recognised that state-employed doctors have consistently got the short end of the stick over the years when it came to remuneration, something to which the Association has always been sensitive. The MASA's hand was strengthened recently when it was recognised as the negotiating agent for the medical profession with the State and, in respect of the additional funds already mentioned, the negotiating team is confident that a portion of these funds will go towards addressing certain structural inequities of the past. This might include the reinstatement of the chief medical superintendent, the chief specialist and the principal specialist to the management echelon, which will entitle these officers to significant additional benefits. The Association is also negotiating for funds to address the disparity between registrars and medical officers, and for overtime remuneration for interns.

Fourthly, significant progress has been made with regard to the vexed question of pharmacists being allowed to diagnose and treat medical conditions. Following intensive legal research, legal consultation and political lobbying, the MASA obtained the agreement of the Parliamentary Committee on Health that the proposed amendments to the Pharmacy Act which would have extended the authority of the pharmacists to practise medicine would have been legally intolerable and morally unjustifiable. The MASA has argued *inter alia* that any amendments authorising pharmacists to diagnose and treat disease without SAMDC training and registration would be *ultra vires* the Medical Act, as would any related regulations by the Medicines Control Council. The Association is sufficiently confident of its position in this regard to be ready to take the matter to the Supreme Court, if the need should arise.

Finally, the MASA is marching in step with the sociopolitical transformation that is unfolding in our country. It has foresworn political affiliation, and has positioned itself as a national professional organisation dedicated to serving the medical fraternity and the entire community. It was in recognition of this ongoing transformation that the MASA was recently invited to join the Confederation of African Medical Associations and Societies (CAMAS), an organisation originally formed as a protest against apartheid and the MASA. The Association views its newly found relationship with CAMAS as an opportunity for future co-operation with other African countries in such areas as medical research, collection and dissemination of information, and the promotion of appropriate health care through our respective governments.

DANIEL J. NCAYIYANA
MARILEEN VAN WYK

The South African Bone Marrow Donor Registry

Allogeneic bone marrow transplantation is the preferred form of therapy for patients with aplastic anaemia or severe immunodeficiency disease and is increasingly being used in leukaemia, the lymphomas and myeloma.[1] In these and other malignancies, escalation of chemotherapy to supralethal levels can be achieved with relative safety by means of autologous procedures, preferably in conjunction with recombinant human growth factors. However, currently available conditioning regimens are not universally effective in the eradication of minimal residual leukaemia, so that interest centres on the generation of graft-versus-leukaemia (GVL), an immunologically mediated phenomenon associated with allografting.[2-5] Unfortunately, this effect is associated only with the more severe instances of graft-versus-host disease (GVHD), resulting in unacceptable rates of morbidity and mortality.

The barrier to allogeneic transplantation lies in a series of cell surface glycoproteins, collectively referred to as the major histocompatibility antigens. In humans, these are designated the human leucocyte antigen (HLA) system, which is encoded by a number of genes located on the short arm of chromosome 6 and comprises two major groups. The first, designated class I HLA-A, B and C loci, is extremely polymorphic. In 1991, there were 22, 50 and 11 alleles reported respectively;[6] these are identified by standard serological methods. The second, or class II antigens, are less variable, with 18, 9 and 6 alleles described for the DR, DQ and DP loci; many of these can only be detected by DNA typing. Gene amplification by means of the polymerase chain reaction (PCR)[7] and subsequent charac-

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terisation of the alleles by hybridisation with complementary DNA sequences or probes, are the preferred methods, because serological techniques are not reliable in an estimated 25% of cases.[8,9]

In general, the results of transplantation are better with fully histocompatible donors and recipients, although in the case of solid organs some discrepancy can be tolerated and graft failure reduced by a variety of immunosuppressive drugs. In contrast, bone marrow transplantation is critically dependent on HLA identity, because even single amino acid differences between antigens are associated with rejection or the development of GVHD.[10,11] One way to overcome these complications is by autografting. Alternatively, an HLA-identical sibling is used as the donor. The clustering of loci in the system on the chromosome generally results in their inheritance as a complete HLA-haplotype.

At present, 60 - 70% of patients needing a transplant lack a suitable sibling, but DNA-typing has made it possible to identify unrelated HLA-identical individuals who can serve as bone marrow donors.[12,13] In these situations, the incidence of graft failure as well as both acute and chronic GVHD are increased. Protracted and intense immunosuppression,[14] including the removal of cytotoxic T-cells from the bone marrow,[15] reduces the incidence and severity of the latter complications. Nevertheless, this new therapeutic option is gathering impetus and, over the last 5 years in Europe and North America, has led to the establishment of registries for this purpose. Initially, volunteers were recruited from apheresis programmes because they had already been tissue-typed, but increasing attention is being directed toward blood donors and the general public.[16] Interested individuals sign a statement of intent to donate bone marrow and a blood sample is collected for typing of the HLA-A, B, C and DR alleles by serological methods. The results are entered into a computer database. When needed, a search is undertaken to identify potential HLA-identical individuals, after which DNA-typing of the DR, DQ and DP loci as well as mixed lymphocyte culture testing are used to confirm histocompatibility. A pool of between 100 and 10 000 donors of the same race as the recipient is needed in order for there to be a realistic chance of finding a matched donor in any search. The likelihood varies, depending on whether the HLA-haplotype of the patient is common or rare.[17] To increase the number of potential donors, national registries co-operate through the World Marrow Donor Association, thereby providing access to some 800 000 potential donors.

Should there be more than one registry in a country, co-ordination is ensured by the hub centre. A prerequisite for such a designation is an intimate association with an internationally accredited transplantation group on the one hand and the availability of the latest tissue typing technology on the other. In South Africa, these criteria are fully met by the Provincial Laboratory for Tissue Immunology, which has started a bone marrow donor registry, together with the University of Cape Town Leukaemia Centre and the Department of Haematology at Groote Schuur Hospital. The justification for such an undertaking is the fact that allele and haplotype frequencies of the HLA system differ considerably between races throughout the world[18] and at present most donors are white. For instance, the frequency of the most common haplotype in blacks, A30, B42, and DR3, is 7,5%; in whites the frequency of this haplotype is only 0,02%. Therefore, a particular problem exists for sub-Saharan Africa, because matched donors for non-white patients are difficult to find.

Despite the fact that there is undoubtedly an increased risk of severe acute and disfiguring chronic GVHD after unrelated matched transplants,[11-13] some recent results obtained after T-cell depletion of bone marrow prior to transplantation have been encouraging.[15] In patients with leukaemia, there is a higher risk of graft failure with well-matched unrelated donors, compared with HLA-identical siblings.[19] The incidence of GVHD and long-term survival rates of the two groups were comparable. However, such figures do not reflect the poor quality of life which results from debilitating GVHD. Because the incidence and severity of this complication increase with the degree of mismatching,[14,20] it follows that meticulous donor selection is mandatory. Alternative HLA-identical donation from within the family and the use of matched unrelated volunteers are relatively recent therapeutic approaches, and their use is tempered by an appreciation of the devastating side-effects that may occur.

Certain studies[16,21] examining donor recruitment include the question of their commitment to donate bone marrow when requested and the estimated 10% annual loss of this population through relocation. In North America, specific problems have been encountered in motivating organ donation among minority groups; objections were mostly of a cultural or religious nature. Because the local registry targets non-whites, a particular effort has been made to anticipate the question of informed consent by having recruiters who are fluent in Xhosa, as well as Afrikaans and English. Comprehensive information leaflets, accompanied by a statement of intent to donate, are available. Lectures have been given to groups in the private sector, colleges and a variety of other institutions to explain the logistics of the donation itself and the risks to the donor, objectively balanced against benefits to the patient. To date, approximately 10% of those addressed have responded favourably. After the blood has been tissue typed, this information is made available to the donor on a card that also carries the address of the registry. Like most registries, the initial search will be without cost, but further investigations to confirm matching will be billed to the recipient.

More information is required to answer questions regarding the definition of an acceptable unrelated bone marrow donor, refinement of T-cell depletion programmes and post-transplant immunosuppressive regimens. Despite these reservations, preliminary results are such that the effort of establishing and maintaining a registry is entirely justifiable.[13,22]

P. CREEMERS
P. JACOBS
A. BIRD
E. DU TOIT
South African Bone Marrow Registry
Cape Town

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ISSUES IN MEDICINE

Keeping the prescribing pharmacist at bay

The campaign to legalise the rendering of medical care by pharmacists has been thwarted. The Parliamentary Joint Committee on Health has accepted the Medical Association of South Africa's representations concerning certain amendments to the Pharmacy Act, which would have created the scope for such practices. The MASA presented expert legal and medical opinions in support of its arguments that the proposed amendments would have been legally intolerable and a public disservice. The basis of the MASA's strategy was intensive lobbying and insistence on maintaining the professional image of the medical profession by refusing to fight the matter through the media. The MASA is confident that the Medicines Control Council (MCC) will now also not introduce draft regulations to the same effect in terms of the Medicines and Related Substances Control Act. Legal counsel advises that this would be *ultra vires*, and that MASA should appeal to the Supreme Court if the MCC introduces the regulations. The background to the most recent events is as follows.

During 1993 the pharmaceutical profession intensified its campaign for authorisation to treat and diagnose medical conditions. Advertisements began to appear in all possible media. The campaign became more of a reality with more and more pharmacists applying for special permits to this effect from the Department of National Health and Population Development (DNHPD). The MASA intervened immediately and the permit issue was partially resolved when the Director-General of the DNHPD placed a moratorium on the issuing of permits, agreeing to issue them personally and only on merit. However, in September the Pharmacy Amendment Bill was published. Only 4 days were given to interested parties to prepare comment on the Bill. After having presented verbal and written representation to the Parliamentary Joint Committee on Health on two occasions, the MASA succeeded in convincing them to withdraw certain amendments which failed to delineate the role of pharmacists.

Some of the main points of criticism of the Bill related to the fact that the legislation would have entitled pharmacists to diagnose and treat patients. Furthermore, vague and unspecific provisions were proposed to broaden the role of the pharmacist. This was totally unacceptable, as it would have created legal uncertainty and a criminal offence.

The MASA also argued that allowing pharmacists to render clinical health care would not alleviate the burden on the State and make health care more accessible — more than 80% of pharmacists are in the private sector and in 24% of the magisterial districts there is no pharmacy.

The MASA is of the opinion that the Pharmacy Amendment Bill was in fact published in an attempt to 'legalise' draft regulations in terms of the Medical and Related Substances Control Act, which was published for comment 3 months earlier. These draft regulations, which are currently before the MCC, have the explicit intention of allowing pharmacists to render clinical medical care. The MASA intends to appeal to the Supreme Court if the MCC proceeds with their implementation. It is envisaged, *inter alia*, that pharmacists would be allowed to diagnose and treat patients, and to prescribe medicines up to Schedule 5 — in some instances even up to Schedule 6. This is not allowed in terms of the Pharmacy Act and can therefore not be effected through administrative regulations not debated in Parliament.

The draft regulations further envisage that the SA Pharmacy Council would accredit training courses for pharmacists. This, too, is prohibited in terms of the Medical, Dental and Supplementary Health Service Professions Act, 1974, which provides that only the South African Medical and Dental Council (SAMDC) may approve the training of persons to 'diagnose, treat or prevent any physical or mental defect'. Accreditation of these courses by the SA Pharmacy Council would therefore contravene the above Act.

Statements by spokespersons of the pharmaceutical profession that pharmacists do not need more than 1 week of training are blatantly untruthful and arrogant. The medical profession promotes continued education even after 7 - 12 years' intensive practical and academic training.

Fragmented control over pharmacists and doctors authorised through separate statutory councils to perform the same actions and carry the same responsibilities, will lead to professional inconsistencies. The South African law does not tolerate double standards. The principle of the 'reasonable man' prevails and doctors are judged against available fields of expertise. A pharmacist giving clinical medical care will be judged against the skills of a reasonable general practitioner and not those of a reasonable pharmacist. The MASA has numerous examples of misdiagnoses and maltreatment by pharmacists that caused permanent damage and in some cases were fatal.

MARILEEN VAN WYK