

## Ethical and regulatory issues surrounding umbilical cord blood banking in South Africa

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Recent medical advances in the field of regenerative medicine and tissue transplantation have highlighted the importance of umbilical cord blood (UCB) as a valuable alternative source of haematopoietic stem cells, which are potentially life-saving in a vast array of clinical applications. Although less controversial than the use of embryonic stem cells obtained from fetal tissue, the practice of UCB biobanking presents several ethical and regulatory challenges surrounding its procurement and use, especially in developing countries like South Africa, where the majority of the population is vulnerable and prone to exploitation. Currently only private umbilical cord banking is practised in South Africa and the regulatory framework for human tissue use is still rudimentary with no clear guidelines. This environment raises ethical questions about consent and ownership of tissues, the cost-effectiveness of harvesting and storage of UCB, undue influence on donors, and issues of distributive justice such as the fact that UCB, which is potentially life-saving and could be easily obtained, may become a resource unfairly restricted only to the wealthy. In view of the fact that UCB has become a valuable, non-invasive source of stem cells for regenerative therapy, establishment of a public cord blood bank (CBB) in South Africa would vastly improve the availability of haematopoietic stem cells for research and therapeutic uses, and increase the tissue genetic diversity that currently impedes the South African bone marrow registry.

### What is umbilical cord blood banking and why is it important?

In the novel and exciting field of regenerative medicine, umbilical cord blood (UCB), also known as placental blood, is no longer considered biological waste.<sup>1,2</sup> UCB is the blood in the cut umbilical cord and placenta after delivery. Derived from the fetal allantois, it provides a rich source of multipotent stem cells, including CD34<sup>+</sup> and CD38<sup>-</sup> haematopoietic progenitor cells. These progenitor cells have greater clonal expansion and proliferative capacity than normal bone marrow cells. As a source of non-embryonic stem cells, UCB has found potential uses as a therapeutic modality in more than 80 clinical applications, both haematological and non-haematological.<sup>2</sup> UCB is at the forefront of research exploring gene therapy, prenatal diagnosis, immune cell therapy, antibiotic efficacy and identification of new proteins.<sup>2,3</sup> Normally, the bone marrow serves as the source for replenishing the cellular components of peripheral blood including red and white blood cells and platelets. Deficiency or malfunction of these blood cells occurs in disease conditions prevalent in Africa, including cancers like leukaemia and haemoglobinopathies like thalassaemia or sickle-cell disease. UCB may also be used to reconstitute the bone marrow after high-dose chemotherapy or radiotherapy. UCB's advantages over other sources of stem cells such as adult bone marrow and embryonic stem cells include easy procurement, minimal risk to the donor, excellent proliferation and differentiation, immediate availability, and autologous use. UCB also has greater tolerance of HLA disparity with lower risk of graft-versus-host disease (GVD).<sup>4</sup> Limitations of UCB include once-off

collection/donation, sometimes yielding small volumes less than 40 ml, containing <120 million nucleated cells. This may lead to inadequate engraftment in some adult patients.<sup>5</sup> Homing and stem cell expansion are being researched to overcome these obstacles militating against wider use of UCB.<sup>6</sup>

In 1983 Koike<sup>7</sup> showed that UCB-derived stem cells could be frozen and stored for future use. Following the first successful transplant/treatment of a child with Fanconi's anaemia using his sibling's cryopreserved UCB,<sup>8</sup> many successful UCB transplants followed, leading to establishment of the first public cord blood bank (CBB) at the New York Blood Centre.<sup>4,9</sup> Subsequently, many public and private CBBs have been established globally.<sup>3-5</sup> In 1996, funding was awarded by the National Institutes of Health (NIH) for UCB banks to conduct national safety and efficacy trials.<sup>9</sup> With improved standardisation techniques, over 600 000 units of UCB are reportedly banked worldwide, while over 14 000 UCB transplants have been performed successfully.<sup>2</sup> The two South African case scenarios reported in Table I illustrate some ethical challenges arising during treatment of patients with life-threatening illnesses in developing countries, and the potential advantages of UCB biobanking.

### Private versus public CBBs

UCB is collected and stored by two primary mechanisms:

**Public (not-for-profit) CBBs** are publicly owned and usually funded by governments. They collect UCB from any willing donor, which are then stored and used for transplantation to benefit

**Table I. Case scenarios illustrating potential benefits of UCB banking in South Africa**

## **Case scenario A**

*Patient A* was first diagnosed with acute lymphoblastic leukaemia (ALL) at age 2. He was treated as a medium-risk patient according to stratification criteria. He achieved remission on completion of maintenance chemotherapy within 4 years of diagnosis and was closely monitored by the haematology/oncology team. Less than a year later, he presented with testicular relapse. At this stage he is in remission but remains at 'high risk' for future relapse. If this occurs, the ideal treatment would be:

1. A human leucocyte antigen (HLA)-matched identical sibling bone marrow transplant (unavailable)
2. An HLA-matched sibling transplant (unavailable)
3. An unrelated bone marrow transplant (preliminary search of local bone marrow registry revealed no matched potential donors; an international registry search is cost-prohibitive and too expensive for his family).

His mother is not in favour of the only available option for him, which is palliative chemotherapy, indicating terminal illness. She has recently raised the possibility of having another baby that could serve as a 'saviour sibling' for him, by providing life-saving stem cells from umbilical cord blood. She is exploring the concept of having this baby naturally or genetically selected as a 'designer baby' guaranteed to be a matching-tissue donor for the son diagnosed with ALL.

## **Case scenario B**

*Patient B* is a 3-year-old girl with severe aplastic anaemia, a clinical condition where the bone marrow cannot produce peripheral blood cells. The child presents with recurrent life-threatening bleeding secondary to thrombocytopenia – very low platelet counts in the blood, which is unresponsive to medical treatment. She has no HLA-compatible siblings following testing, and her parents are currently raising funds for a local bone marrow registry search. However, because of her ethnic origin and the lack of genetic diversity within the potential donor pool, the likelihood of finding a matching donor is very slim.

any suitable public recipient for whom the blood/stem cells are a match. The majority of recipients benefiting are unrelated allogeneic transplant patients. UCB collected by this mechanism can also be used for laboratory-based research benefiting society in general.

**Private (for profit) CBBs** usually collect UCB on behalf of expectant parents for potential use by a child for autologous transplantation or a family member in need of stem cell transplant through directed allogeneic transplantation.

Table II outlines the operational differences between private and public CBBs.

## **Ethical dilemmas arising from UCB biobanking**

### **Beneficence and non-maleficence**

One ethical basis for UCB use is the physician's obligation to provide benefit to the patient while minimising risk/harm caused by other disease conditions.<sup>3</sup> The use of UCB-derived stem cells in research has the potential to help conquer a broad spectrum of previously incurable conditions, thereby alleviating human suffering. However, the physician's obligation of non-maleficence (do no harm) may be contravened if effective quality control (QC) is not rigorously maintained. This may occur in private CBBs where a conflict may arise between the need to maximise profits and maintaining the expected 'standard of care' in QC, including assessment of cellular viability, sample volume, methods of acquisition and transportation, leading to poor overall quality of collected UCB units.<sup>3</sup> These dangers are magnified in developing countries like South Africa where the regulatory framework is not clear and applicable laws are not rigorously enforced.<sup>10</sup> It has been observed that while public CBBs are regulated by stringent international QC standards, private CBBs use less stringent QC methods when col-

lecting and storing UCB. These violations of established standards include use of untrained personnel to collect UCB at the time of birth and storage of inadequate volumes, leading to a situation where clients of private CBBs may finance storage of samples later found insufficient for the purpose envisaged.<sup>5,9</sup> The use of UCB for autologous transplant in malignant diseases or inheritable genetic disorders has also been criticised because the cancerous potential of the UCB cannot be completely excluded because of genetic factors in donors.<sup>11</sup> A lack of clinical and genetic information about unrelated donors at public CBBs may also result in the transfer of abnormal cells even where careful screening has been implemented.<sup>9</sup> In the above circumstances the ethical obligations for beneficial use of a valuable healthcare resource may come into conflict with the ethical obligation to avoid harm, creating dilemmas that need to be carefully considered before choosing an appropriate regulatory framework for collection, storage and use of UCB.

### **Respect for autonomy, informed consent and ownership**

Ownership of UCB is sometimes debatable since the umbilical cord is embryologically derived from the fetal allantois; it may be considered property of the child. However, UCB is usually collected with the consent of the mother.<sup>5</sup> One alternative view is that UCB is the property of the mother once the cord is cut, and a 'gift' to the child.<sup>12</sup> In many private banks, ownership transfers to the child once he/she comes of age. However in English as well as South African law, legal personhood begins at birth. 'A fetus which is born and lives *ex utero*, even if only briefly, becomes a legal person and acquires all the rights and status thereto attached.'<sup>13,14</sup> However, although a newborn baby is recognised as a legal person by law, he/she does not have the capacity to provide informed consent. Storage of his/her UCB for several years could be arguably considered a manipulation of human tissue without the owners' consent.<sup>12,15</sup> Future conflicts could foresee-

**Table II. Main operational differences between private and public banks**

	Public banks	Private banks
Financing systems	State funded	Collection, testing, transport and storage costs all paid by donor (parents)
Access	Available to any suitably matched recipient in need	Only to those who can afford service. Majority of units collected remain unused (wasted)
Acquisition of samples	By trained personnel at selected designated hospitals – donors restricted to delivery at designated sites	By third party (potentially untrained); also possibility of financial incentive for personnel engaged in UCB collections
Quality assurance	Better adherence to quality standards, cellular viability control  Only samples that meet specified criteria in terms of volume/quality are stored	Not always affiliated to international groups certifying adherence to quality standards  All samples are stored irrespective of volume/total nucleated dose
Availability	Not immediate, depends on HLA bioarchive	Immediate – where the CBB is located locally in the same country  Potential delays – where the CBB is stored in a different country overseas because of absent local infrastructure, e.g. South Africa
Compatibility	Ranges up to 90% with HLA bioarchive	100% assured – when used by other family members
Consent	Often obtained at time of delivery – not optimal	Obtained well before birth – adequate reflection  Potential for coercion, undue influence or manipulation – advertised as ‘biological insurance’  May make unsubstantiated claims of use in conditions that are in fact speculative

ably arise where such tissues are needed for use by an ailing sibling, as demonstrated in the case of *McFall v Shimp* where an individual who was identified as a compatible bone marrow donor to his cousin diagnosed with aplastic anaemia, refused to serve as a transplant donor for the treatment of his dying cousin. The court found it would be unjustifiable to compel any individual to serve as a donor contrary to the principle of self-determination and freedom of choice.<sup>16</sup> Similarly in *Re Y*, the court ruled that a mentally disabled sibling could not serve as a bone marrow donor for her sister who was diagnosed with a pre-leukaemic disorder, except if it was in her ‘best interests’ to do so.<sup>17</sup> Another potential area of conflict lies within the provisions of the current National Health Act of 2003 which allows a donor to withdraw donated tissue at any time before its use.<sup>15</sup> In other words, the parent/mother could provide consent for storage of UCB in anticipation of future use by another family member. However, the adult child would then be required to authorise use of such tissue in the future, where any adult patient has the legal right of refusal even when the stored tissue is to be used for the benefit of a sibling. This scenario presents some potential ethical and legal conflicts which have to be carefully regulated through specific guidelines, that might best be obviated through upfront regulations laid down *a priori* by any ‘authority’ charged with regulation of public and private CBBs. It could be argued that ideally such a regulatory framework should be outlined within the proposed ‘regulations relating to tissue banks’ with reference to section 8 of the National Health Act of 2003, as recently published for comments by the Minister of Health in the *Government Gazette* of April 2011.<sup>18</sup>

## Information disclosure and understanding

Generally proponents of private CBBs argue that the quality of graft is superior with autologous use which assures about 100% compatibility; therefore use of stored UCB would extend to other family members. Most transplants from privately stored UCB are reportedly performed on siblings of the donor.<sup>11</sup> Private CBBs advertise that availability and use of stored UCB will be immediate, but in developing countries like South Africa, where UCB is sometimes stored overseas because of absent local infrastructure, there could be delays in availability. Currently there are about three private CBBs in South Africa, of which one or two store UCB locally while the rest store collected UCB abroad. It is not clear whether this information is clearly communicated or understood by clients/parents. Further, the procedure for external storage in these cases could also be considered exportation of tissue with subsequent importation which could run contrary to the provisions of the National Health Act.<sup>15</sup> While most international ethical committees discourage the activities of private CBBs by requiring strict regulation and close supervision, freedom of enterprise and choice of individuals and parental rights must also be respected. Parental consent on behalf of children needs to be adequately informed and obtained by qualified persons well in advance of the emotional birth process, to allow adequate time for reflection and minimise undue pressure. Comprehensive information booklets provided to prospective donor parents should be made available at antenatal visits to facilitate full information disclosure. Preferably this booklet should be translated into local languages to facilitate comprehension. It has been suggested that the validity of consent obtained by private banks may be

questionable because of emotional coercion, as the service is often touted as 'biological insurance'.<sup>5</sup> Information given to parents must include details of the collection procedure, costs, storage methods and potential uses of UCB, including possible use for research. Prospective donor/parents should also be informed of their inability to direct the use of UCB stored in a public CBBs.<sup>3</sup>  
<sup>5</sup> When blood is collected by public CBBs consent is often obtained around the time of delivery which may be unethical, since the emotional process at birth could unduly influence the mother's ability to provide valid consent.<sup>5</sup>

## Distributive justice and human rights

Storage of UCB for autologous use in private CBBs is viewed by several international ethical authorities as a wasteful practice of self-preservation<sup>19-23</sup> which may promote social discrimination based on wealth. The odds of needing a non-autologous UCB transplant range from 1:1 000 to 1:20 000. The likelihood of finding a suitable HLA-matched donor in a public CBB is higher, since there is a greater tolerance for HLA disparity with UCB. On the other hand, the likelihood of requiring autologous UCB transplant is extremely low (as little as 0.0005%).<sup>4,5</sup> Private banks are generally seen as competing with public banks for a valuable biological resource which contradicts the principles of altruism in human tissue donation.<sup>3</sup> Society has an obligation to protect the vulnerable and ensure equal access to healthcare. Voluntary donation of UCB to public banks resembles regular blood donation which is altruistic and promotes social justice. Private banking for autologous/family use creates problems of inequitable access to healthcare services. The European Group on Ethics (EGE) advises that the donation of human tissues must be free and altruistic. Donors should not receive remuneration; this would avoid exploitation of the disadvantaged in society.<sup>3,24,25</sup> This reaffirms the principles of non-commercialisation of human tissues, and respects human dignity.

## Privacy and confidentiality

Consent and privacy are important issues for all DNA biobanks, not just CBBs.<sup>26</sup> Privacy is of special concern in collecting, testing, and storing UCB because the source of blood is a newborn. While there are no physical risks in collecting UCB, there are significant risks to privacy. It is generally agreed that it is unethical to test children for genetic disorders for which there are no current preventive measures or therapy. It is possible that some additional useful information about safety of UCB could be gained by following such children as they grow older. However, surveillance seems impractical and may constitute an invasion of privacy.<sup>26</sup> Further, when UCB is used for research or therapy, it must be screened for a variety of diseases, including HIV/AIDS and other genetic disorders. Some private banks do not store HIV-infected blood. This may be construed as a form of discrimination, especially in countries like South Africa where the burden of HIV/AIDS is very high. HIV-infected patients are also predisposed to malignant disease and blood dyscrasias, and may arguably benefit more from UCB transplantation. Records of UCB donors and recipients must be kept confidential and afforded the full protection of the law.<sup>23</sup> If a genetic abnormality or infection is discovered during testing, the results must be delivered to the donor/parent/guardian in a manner that is appropriate in relation to the severity of the abnormality with appropriate counselling. Consideration should be given to an 'opt-in/opt-out' choice for disclosure of abnormal results to respect patient autonomy and freedom of choice.<sup>9</sup> Again, informa-

tion regarding the available choices should be included as part of the comprehensive information booklet and should become part of the informed consent process. It could be argued that in private CBBs, this notification and requirements for information disclosure may not meet rigorous ethical standards for disclosure because the objective of such entities is commercial success. Therefore such standards of information disclosure must be clearly legislated and enforced.

Other potential ethical conflicts regarding privacy and confidentiality have been highlighted. For example, during a study by Rubenstein and others,<sup>4</sup> tests for haemoglobinopathies and other genetic diseases were performed on the basis of family history and ethnic background. Where UCB is linked to the donor, screening creates a medical information pathway about the child which has the potential to expose the mother's 'private history' as well.<sup>26</sup> This leaves two options: either the mother's fully informed consent needs to be obtained to perform the screening tests and steps taken to inform her of the test results while keeping them confidential from others, or the UCB must be anonymised so that it cannot be linked to its source. Finally, it has been suggested that the best policy for the storage of non-autologous UCB, from the standpoint of privacy, would be complete de-identification of samples, so they could be freely tested without simultaneous testing of the mother and child.<sup>26</sup> The issue of privacy and confidentiality of UCB biobanking contains potential pitfalls that could lead to many ethical and legal dilemmas. These need to be further regulated by specific guidelines separate from those available from general confidentiality laws.

## Ethical and regulatory perspectives from international bioethics committees

The practice of UCB banking has come under scrutiny for ethical conflicts by some international bioethics committees, including those from the European Union.<sup>19-25</sup> Opinions of different committees appear unanimous in their evaluations of controversies surrounding private and public banking. In 2004, the European Group on Ethics in Science and New Technologies (EGE) advised the European Commission that 'the legitimacy of commercial CBBs for autologous use should be questioned' and warned that advertising must be adequately controlled by public authorities. They also recommended that support for public CBBs for allogeneic transplantations should be increased.<sup>25</sup> The Royal College of Obstetrics and Gynaecology (RCOG) advised that the collection of non-directed and directed donations for 'at-risk families' are acceptable through public CBBs, but there is insufficient evidence to recommend collection and storage for 'low-risk families'. Emphasis was placed on the fact that patients must be fully informed of their rights and financial obligations in the case of private banking, and research should continue on UCB use for stem cell therapy.<sup>22</sup> By 2004, the European Union (EU) issued directives on tissues and cells aiming to establish a harmonised approach to regulation across Europe. The directives set benchmarks for standards that must be met when carrying out any activity involving tissues and cells for human application or patient treatment. The regulations also require that systems be put in place to ensure that all tissues and cells used in human application are traceable from donor to recipient.<sup>27</sup> These directives were adopted into UK domestic law in 2007. They make

provisions for procurement, testing, processing, storage and distribution, including import and export of human tissues.<sup>28</sup> Many reports indicate that private CBBs usually collect UCB for parents as an 'insurance policy' against future catastrophes. The American College of Obstetrics and Gynecology (ACOG) opined that: *'Parents should not be sold this service without a realistic look at the "return" of their investment and that commercial cord blood banks should not market their highly speculative market services as "doing everything possible".'*<sup>19</sup>

Similarly, the American Academy of Pediatrics (AAP) concluded that philanthropic donation of cord blood for banking at no cost for allogeneic transplantation should be encouraged<sup>20</sup> while a recent policy update<sup>21</sup> stated: *'Cord blood donation should be discouraged when cord blood stored in a bank is to be directed for later personal or family use, because most conditions that might be helped by cord blood stem cells already exist in the infant's cord blood ... Given the difficulty of making an accurate estimate of the need for autologous transplantation and the ready availability of allogeneic transplantation, private storage of cord blood as "biologic insurance" is unwise.'*

## Some important issues that may require specific regulation

**Advertising.** Advertising must be clear about the potential benefits for clients of private CBBs and should indicate explicitly the negligible odds that the sample will be needed for autologous use, and that some future therapeutic possibilities might be found to be remote. Advertising needs to be controlled by local authorities.<sup>22</sup>

**Commercialisation and patenting.** Further clarification needs to be made regarding the commercial gains from UCB research from donated units.<sup>24,29</sup>

**Relationships between patients, doctors and CBBs.** Financial incentives for medical personnel collecting UCB for private CBBs have been implemented by some private banks (anecdotal evidence) however the American Medical Association (AMA) advises that: *'Physician's ties to public and private cord blood banks must be disclosed during the informed consent process and physicians should not accept financial or other inducements for providing samples to CBBs.'*<sup>12</sup> Information must be provided to private clients regarding the storage and safety of their 'investment' in the event of termination of business either by bankruptcy or natural disasters. Perhaps new regulations should include provisions for insurance and compensation in case of loss or damages.

**'Designer babies' and 'saviour siblings'.** The issue of designer babies and saviour siblings creates moral conflicts that require careful ethical consideration. Concerned parents may request that physicians create a test-tube baby with the pre-implantation characteristics necessary to serve as a 'saviour sibling' for an ailing child. Should routine acceptance of these requests become the norm, it may lead down a slippery slope and open floodgates with implications for eugenics. Further, it has the potential to result in severe emotional distress and possible stigmatisation for both the donor and recipient siblings in future life.

## The case for establishment and regulation of public/private CBBs in South Africa

Stem cell use in South Africa is currently governed by the Human Tissue Act (Act 65 of 1983)<sup>30</sup> which states that written consent from the donor(s) be given for the removal/withdrawal of tissue unless such tissue is replaceable by natural processes, in which case consent may be oral.<sup>29</sup> Further, placental, fetal tissue and umbilical cord tissue may only be withdrawn with the consent of the Minister subject to any conditions mentioned in the consent.<sup>24</sup> Since healthcare priorities in most developing countries remain preventive medicine and the provision of basic healthcare services, UCB banks have been predominantly established in developed countries with the exceptions of Mexico, China and Argentina.<sup>3,31</sup> In view of the costs involved in establishing and maintaining a CBB that would mirror the genetic diversity of the local population, relative to the benefits and actual potential for use, the establishment of public CBBs in South Africa has so far not been feasible. For those who can afford them, private CBBs are the only option for storage of UCB, and this further increases inequitable access to healthcare services in South Africa. While the Bill of Rights guarantees a right of access to healthcare services, the problem is that despite the potential benefits of UCB biobanking, the government cannot fund all healthcare services where there are many competing needs such as the large burden of HIV/AIDs, tuberculosis and other disorders as demonstrated by the *Soobramoney* case.<sup>32</sup> However, there may be room for public-private partnership (PPP) in such a way that the government provides the appropriate regulatory framework and guidelines, while non-governmental organisations (NGOs) endeavour to establish and run public CBBs within specified rules with the resulting goal of enormous public good. This is especially of relevance in terms of the future plans for implementation of the proposed National Health Insurance (NHI) scheme in South Africa. The government could also explore other creative mechanisms for funding such as imposing levies or a tax on all private UCB collections stored in South Africa, with a percentage of the revenue generated used for establishment of a public CBB run on a (PPP) fee-for-service basis. These regulations could be incorporated into the new guidelines envisaged when section 8 of the National Health Act, dealing with human tissues, comes into effect in the near future.<sup>18</sup> Further, establishment of public CBBs or preferably a central national CBB with satellite branches within different provinces in South Africa would vastly improve availability of genetically diverse tissues for transplant, and help to resolve the problem of genetic diversity that currently impedes the South African Bone Marrow Registry.<sup>33</sup> Another consideration in the context of establishing a public CBB in South Africa is the high prevalence of HIV and hepatitis B.<sup>34</sup> The protocols for screening donated UCB for transmissible infections will need to be stringent and may be costly, thereby requiring creative funding and specific regulation.

It has been argued that since stem cell research is financially lucrative for private enterprises, the potential uses of UCB in research and therapy may present another opportunity for exploitation of vulnerable Africans. In the absence of an appropriate regulatory framework, commodified human tissues including stem cells from UCB may be surreptitiously exported elsewhere for commercial research purposes.<sup>29</sup> Private CBBs could potentially capitalise on this regulatory vacuum to exploit local donors/clients without their knowledge.<sup>24</sup>

## Conclusion

UCB biobanking as a measure to achieve the common good is an example of a social justice health model. As with any other scientific advances, it is necessary to closely analyse the impact on social, ethical, moral and legal frameworks before implementing such public policies. In South Africa, the concept of UCB biobanking must be explored in order to keep pace with the needs of a changing population, and to contribute and benefit from international collaborations in tissue transplantation. For these reasons a specific regulatory framework providing guidance on UCB storage and use needs to be developed. This must provide specific guidelines for ownership, informed consent, procurement, testing, storage and distribution including import/export and the financial implications for donors and recipients. Part of the problem for the current state of affairs is due to the vacuum created by the non-implementation of section 8 of the National Health Act of 2003. While new regulations may trigger some negative reaction especially from commercialised private CBBs, who may perceive a centralised public CBB as competition, the potential for enormous public good would override these concerns. Further, establishment of a centralised public CBB through a PPP mechanism will help the new NHI scheme towards achieving its goal of equity of access and availability of healthcare services to the majority of South African citizens. This will be achieved through appropriate regulations. Any conflicts triggered by the new regulations could be dealt with at central level through an inclusive process of discussion between the public and private stakeholders. A previous reviewer of this paper has suggested that investigating the conversion and absorption of the current Bone Marrow Registry into a centralised public CBB would be beneficial if achievable; however achieving this laudable objective may require the appointment of either a Presidential or Ministerial Advisory body, preferably a Presidential Advisory Board with the Minister of Health chairing it in order to deal with the socio-political implications involved.

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