

The background is a quilted fabric with several distinct patterns. There are sections with small, repeating circular motifs, sections with larger, detailed leaf shapes, and sections with a simple dot pattern. The overall color palette is muted, consisting of various shades of grey, beige, and light brown.

Chapter 10

REMUNERATION OF HEMATOPOIETIC STEM CELL DONORS: PRINCIPLES AND PERSPECTIVE OF THE WORLD MARROW DONOR ASSOCIATION

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Abstract

Hematopoietic stem cell transplantation is a curative procedure for life-threatening hematologic diseases. Donation of hematopoietic stem cells (HSCs) from an unrelated donor, frequently residing in another country, may be the only option for 70% of those in need of unrelated hematopoietic stem cell transplantation. To maximize the opportunity to find the best available donor, individual donor registries collaborate internationally. To provide homogeneity of practice among registries, the World Marrow Donor Association (WMDA) sets standards against which registries are accredited and provides guidance and regulations about unrelated donor safety and care. A basic tenet of the donor registries is that unrelated HSC donation is an altruistic act; nonpayment of donors is entrenched in the WMDA standards and in international practice. In the United States, the prohibition against remuneration of donors has recently been challenged. Here, we describe the reasons that the WMDA continues to believe that HSC donors should not be paid because of ethical concerns raised by remuneration, potential to damage the public will to act altruistically, the potential for coercion and exploitation of donors, increased risk to patients, harm to local transplantation programs and international stem cell exchange, and the possibility of benefiting some patients while disadvantaging others.

Background

Hematopoietic stem cell transplantation (HSCT) has been in use since the 1960s and is a proven cure for patients with hematologic and metabolic disorders and immune deficiencies. A necessity for performing HSCT is that the donor and the recipient have identical or close to identical human leukocyte antigen (HLA) phenotypes. The first allogeneic HSCTs were performed with HLA matched related donors only. There is a 25% chance that 2 siblings inherit the same HLA phenotypes, and ~30%-35% of patients will have an HLA identical sibling or closely matched family donor. For patients requiring an allograft who do not have a related donor, an HLA matched unrelated donor or cord blood unit has been an option for 4 decades.

The single most important donor factor in determining transplantation outcome is the degree of HLA matching between patient and donor^{1,2}. The HLA system displays extreme polymorphism, such that for many patients, there may be few if any other persons who will match their unique HLA type. To assist patients in finding a potential unrelated donor, registries of HLA typed volunteer donors were first established in the early 1970s. It was soon realized that the opportunity for finding a matched donor would be significantly enhanced by creating a mechanism for searching donor registries in other countries. This was achieved by the formation of Bone Marrow Donors Worldwide in 1988. Bone Marrow Donors Worldwide provides a centralized database containing information on the HLA phenotypes of virtually all unrelated donors (adult and umbilical cord blood, a source also rich in hematopoietic stem cells [HSCs]), allowing the entire international inventory to be searched in one single location.

Currently, there are more than 14.9 million registered unrelated donors internationally, in 64 stem cell donor registries from 44 countries and in 44 organizations of cord blood banks from 26 countries³. In 2008, more than 11,500 patients worldwide received an HSC transplant from an unrelated donor. Greater than 44% of those patients used a donor or cord blood unit from another country⁴, emphasizing the benefit of international cooperation in all aspects related to the procurement, transport, and use of these stem cell products.

Despite the number of adult donors already registered and the growing numbers of publicly stored cord blood units worldwide, many patients in need of an HSCT still cannot find an acceptable HLA matched donor because they have a rare HLA phenotype. The inability to find an HLA match for specific patients has led to the development of strategies to enhance the registries by increasing both the number and diversity of the donors listed^{5,6}.

Remuneration of donors is sometimes proposed as a means of incentive so more persons join and donate HSCs. In this context, the issue of remuneration of HSC donors has been raised in a lawsuit filed in the United States District Court in October 2009⁷.

In that case, the plaintiffs sought to overturn the prohibition against remuneration for marrow donors found in the National Organ Transplant Act⁸, arguing that the prohibition limited access to persons who might donate if they were remunerated.

The question of remuneration of donors is also currently being openly debated in the context of solid-organ donation. For example, the concern about international trafficking of organs and organ donors has recently led the World Health Organization (WHO) to issue a declaration opposing the international exchange of organs⁹. In 2008, in the United States, legislation was prepared that gave states the right to provide remuneration of organ donors as a means to address the organ shortage¹⁰. Although this legislation was ultimately not introduced, it is reasonable to expect that developments in the organ donation arena will have implications for donors of HSCs as well.

The WHO first formally considered the issue of remuneration for organ, tissue, and blood donation in 1991, taking the position that the human body and its parts should not be subject to commercial transactions¹¹. This was reaffirmed by the WHO in 2008 through the restatement of a set of Guiding Principles¹². The European Union has also taken a position against remuneration in the donation of human tissue and cells¹³. Many countries and other jurisdictions have taken similar positions^{14,15}.

The World Marrow Donor Association (WMDA) was established to develop international guidelines and policies to ensure unrelated donor and stem cell product safety and to encourage proactive international collaboration toward harmonizing regulatory standards¹⁶. The WMDA has consistently maintained a policy against remuneration of donors^{17,18}. This position is based on the general consensus of its member organizations that a truly volunteer donor-based system would be the most effective and safe way to develop donor registries. Studies have shown that, although donors express several motivations when asked¹⁹, altruism, the selfless regard or concern for the wellbeing of others, is the fundamental principle behind donation²⁰.

In light of the current debate about remuneration, the WMDA formed a task force to review the question and to develop a policy statement in this matter for its consideration and adoption. Here, we discuss why volunteer persons who provide HSCs to unrelated recipients should not be paid for their humanitarian act.

Common terms

Hematopoietic stem cells (HSCs) mean hematopoietic stem cells derived from bone marrow and peripheral blood unless stated otherwise.

Reimbursement means payments for out-of-pocket expenses incurred by the donor, replacement of lost wages or time off, or payment for medical expenses incurred by or on behalf of the donor related to the donation.

Remuneration means payment of something of value to a donor or other party in exchange for HSCs over and above reimbursement for out-of-pocket expenses.

Ethical considerations

The question of remuneration for donation raises certain ethical concerns. The essential act at issue is the decision by an unrelated person to undergo a medical procedure for the benefit of someone else. A significant body of work has developed around the ethical issues involved in such an exchange, especially in the context of solid-organ donation²¹ and use of donors as research subjects²².

Three ethical principles in particular are often the focus of inquiry. The first is the principle of dignity, which is that the transfer of part of a human body is distinct from that of a product or service and requires unique considerations so as not to devalue human life through commercialization of organ, tissue, and blood. The second principle is that the donor should not be subject to unnecessary or unreasonable harm. Finally, any system of distribution should be fundamentally fair. In particular, no segment within society should benefit at the expense of another segment or permit coercion of any kind in the process of acquiring HSCs.

Dignity

The concept of dignity is premised on the view that the human body should be treated as having intrinsic value apart from the potential economic value that might be placed on organs, tissue, or blood by someone in need. This notion is founded in both religious and philosophical considerations. Many religions hold that the body is a sacred gift from a higher being and a person has the duty to protect or conserve that gift²³. Any harm to the body is a violation of that duty, except in the case of protecting the person from further harm²⁴. From a philosophical perspective, reference is often made to the teaching of Immanuel Kant whose formulation that society should “treat humanity ... always as an end and not as a means only”^{*} is often cited as the basis to conclude that the payment for body parts is a misuse of a human being because it views the provider as a source of supply for the person in need and not a distinct human being²⁵. By considering only the economic value of a donated organ, tissue, or blood, the potential exists that markets for body parts will be created. In such a setting, the sale of a body part is seen as devaluing human life by implying that a person’s worth is based on the material value of the body rather than as a rational human being. Donation without remuneration is generally permitted in the religious setting as an act of charity benefiting a fellow human, whereas in the philosophical setting the nonremunerated donation is seen as an

*) I. Kant, Werke, hrsg. von W. Weischedel; Band IV, Grundlegung zur Metaphysik der Sitten, S. 61. Darmstadt: Wissenschaftliche Buchgesellschaft; 2005. “Handle so, dass du die Menschheit, sowohl in deiner Person, als in der Person eines jeden andern, jederzeit zugleich als Zweck, niemals bloss als Mittel brauchest”.

altruistic act for the benefit of another rather than as a commodification of one human for the benefit of the other.

The concept of dignity must be balanced with the person's right to make decisions about his or her own body, reasonably free from the control of society. However, although recognizing that the person has the right to make decisions about his or her own body within a wide spectrum of behavior, society has an interest in avoiding behavior that has certain social consequences that include undermining widely and deeply held views about the value of life²⁶. The overriding concern is that the person be valued as a distinct human being.

In the context of dignity, a further argument for remuneration is often advanced as it relates to access to health care for economically disadvantaged populations in which minority ethnic groups tend to be overrepresented. In the case of organ donation, denying compensation on the basis of human dignity may deny access to those minority populations that would benefit from donation from persons within the same ethnicity. If that group would respond to compensation, the argument goes, the harm is offset by the benefit to people in the same ethnic group²⁷. This has some resonance in regard to unrelated donor HSCT because patients will probably find a donor within their own ethnic group, and registries struggle to find donors within their minority populations. To sustain this view, it must be argued that the economic value derived from the sale of body parts is more important than upholding the concept of personal and societal dignity of human beings. But this is precisely the trade-off that undermines the value that society puts on the human being. It may also lead to the further commodification of the person or disadvantaged group by opening up the potential of remuneration for other body parts, further undermining the value of the person or population²⁸.

Harm to donor

As noted earlier, the act of donation is to submit to a medical procedure for which the person will not derive any direct benefit. Thus, any harm that might result will not be offset by a benefit to the person undergoing the procedure, except for the sense of satisfaction derived from an altruistic act. Therefore, care must be taken to minimize the potential of harm and to fully disclose any risk to the donor so as to ensure that the decision to donate is made freely and willingly. The decision to take the risk inherent in the procedure must be made without any undue influence or pressure²⁹.

There is a general agreement that donor registries should have donor safety as their first priority^{18,30-32}. Any medical or psychosocial condition that increases the risk to donor has to be thoroughly investigated, resulting either in deferral or approval for donation.

Guidelines for donor risk assessment and deferral are used in conjunction with an individual medical and psychosocial assessment of donor eligibility to make sure that a donor is not asked to take unacceptable risk³³. If the risk is known to the donor, remuneration has the potential of creating a calculation in which the short-term economic benefit is overvalued compared with the risk being taken by the remunerated donor³⁴. The potential for remuneration may also cause the prospective donor to withhold personal health information for fear of being disqualified from donation, preventing an accurate risk assessment and disclosure of risks specific to that donor. As a related matter, the promise of remuneration raises the question of whether the decision to donate is really voluntary when the donor is under some duress due to significant personal economic concerns.

Harm to the donor could occur when the cost to the donor in lost wages, medical bills associated with the donation, or incurring other out-of-pocket expenses would adversely affect the donor. It is widely recognized that the donors should be reimbursed for these types of expenses and are not considered remuneration for purposes of this discussion.

Fairness

Fairness is the concern that the burden of donation not fall on a particular group or class, especially when the benefit accrues to a different group or class. Concern about exploitation of populations underlies both the WHO Guiding Principles and the Declaration of Istanbul⁹. When payment is used as an inducement to provide organs or tissue, it is argued that a wealthier population will exploit poorer populations that will be more susceptible to the perceived short-term gain from the exchange while overlooking the long-term risks and psychosocial implications as discussed further in "Limited benefit of remuneration to donors".

Exploitation of patients is another concern, especially in the HSCT setting. The donor is in the potentially unique situation of being the only possible donor who matches the HLA of the patient, providing significant leverage over the patient; that is, the donor would have the ability to name the price, and market principles would not apply. The donor would have the ability to name his or her price. Patients undergo a preconditioning regimen in the days leading up to the HSCT, which eradicates or suppresses their own hematopoietic system and makes them totally dependent on the cells from the donor to generate a new donor-derived hematopoietic system. The administration of a commercialized donation system while the patient's life hangs in the balance could seriously jeopardize the patient.

Evidence of the exploitative potential of a remuneration-based system has been seen in other settings. For example, in the United States a potential related donor sought compensation for a commitment to donate³⁵. At the time when called to

donate, the potential donor extracted further payment. Tragically, the potential donor ultimately refused to donate. Regardless of the final outcome in this case the situation shows the potential vulnerability of a recipient if the basis of the exchange is financial and not altruistic.

Finally, it has been asked that because personnel and institutions involved in HSC donations are paid for their services, why not the donors³⁶? This question, however, does not seem relevant, because donors are already reimbursed for their out-of-pocket expenses and compensated for income-loss while away from work for donation reasons. The donors therefore continue to earn their salary like all others involved in the donation, but they earn it despite their absence from work.

Other considerations

Safety of patients

Remuneration has the potential of interfering with this process of risk assessment to the detriment of the patient. In a system that uses remuneration, some persons could find the monetary remuneration so significant that they might hide relevant medical or psychosocial information or both^{37,38}.

A process that might induce a potential donor to be less forthcoming in response to the screening questionnaire may result in a patient being placed at risk for the transmission of diseases from the donor. Additional screening and testing may reduce, but cannot eliminate, the possibility of harm to the patient.

Although there may be times when the potential of the transmission of disease is outweighed by the benefit to the patient, that decision must be made with the full knowledge of all potential risks to the patient so that a truly informed decision can be made. The prospect of remuneration may cause the donor to provide information late in the process to increase the chance of being selected to donate. Anything that interferes with full disclosure of that potential risk early in the process may needlessly put a patient at risk.

In a similar context, the question of safety to patients in blood donation has resulted in the development of the international consensus that blood donation be voluntary and uncompensated to protect the patient, as most recently evidenced in the Melbourne Declaration³⁹ of the WHO, which called on "all governments to achieve 100% voluntary nonremunerated donations by 2020 as the cornerstone of their blood policies"⁴⁰.

Limited benefit of remuneration to donors

The effect of financial incentives on HSC donor life circumstances is probably minimal and transient. Evidence from the Iranian system of paying unrelated donors for kidneys led a past president of Organ Procurement Transplantation Network in the United States to state that "The experience in Iran and elsewhere suggests that the poor remain poor following a ... sale and then with one less kidney"⁴¹.

Not only are the financial incentives offered for HSCs unlikely to change the donors' life circumstances, but donors in these circumstances are also unlikely to accrue the known lasting psychosocial benefits of HSC donation. There is ample evidence that unremunerated unrelated HSC donors experience enhanced well-being from altruistic donation and incorporate the donation experience into their self-concept. One of the first large investigations of 849 unrelated bone marrow donors found that many donors felt that by donating bone marrow, they were actualizing a central trait in their identity having to do with willingness to help others⁴². Many of these donors believed that the centrality of this helpfulness trait made them distinct from others and more willing to assist. Donors often identified the source of this focus on helping as stemming from a strong emphasis on generosity and altruism within their family of origin.

A second investigation with a similar group of 493 unrelated bone marrow donors found that high proportions of donors reported (1) that they felt like better persons for having donated (71%), (2) that marrow donation made them feel more worthwhile (67%), (3) that donating marrow was a high point in their lives that made everything seem more meaningful (75%), and (4) being proud of having donated (96%)⁴³. These extremely positive feelings about donation are directly linked to donors' willingness to engage in future altruistic acts, including donation, and to recommend donation to others. More than 90% of donors in this and other investigations report that they would be willing to donate again if they were asked, and if given the opportunity, they would strongly encourage others to donate. In fact, these self-benefits of the marrow donation process were in many cases greater than those observed for living related kidney donors. This is because, unlike in the case of living related donation, the unrelated donor is under no obligation to the recipient and does not stand to tangibly gain from their donation. Thus, these donors are often viewed as exceptional and as having gone above and beyond the call of duty by family, friends, and coworkers⁴³.

Evidence suggests that a further potential benefit of the altruistic motivations that lead to unremunerated donation and the positive feelings resulting from the donation itself is that donors may come to view themselves as "medical donors," a self-image that may increase their willingness to engage in other forms of medical donation (eg, blood donation, cadaver organ donation¹⁹). This will probably be lost

in a system that offers remuneration. Finally, it is a general experience that stem cell donors frequently are willing to accept considerable discomfort without complaining, probably because the act of donation has been so meaningful and valuable for the donor. Perhaps this kind of attitude also can promote a speedy recovery.

Effect on existing registries

Commercialization of donors through remuneration may also create a disincentive for those who are altruistically motivated from joining or continuing to participate on the registry. This behavior has been observed in the blood donation setting⁴⁴. Similarly, it has been observed that the expectation of rewards can undermine the intrinsic value derived from the behavior, reducing interest in participating⁴⁵, or reduce motivation to continue with participation once the reward is received⁴⁶. In the latter case, sometimes referred to as "the overjustification effect" a reward paid for the initial donation may result in less motivation to provide a second donation, which is needed in some of the transplantation cases. It is not clear what effect offering payment for HSC donation would have on the overall numbers of persons willing to provide HSCs. However, the motivations for willingness to provide HSCs would be altered, and a significant reduction in the number of donors willing to donate is highly probable for 2 reasons. First, the very nature of stem cell donor registries (only a small fraction of registered donors will ever donate, and there can be years or even decades between registration as stem cell donor and donation) makes it difficult to motivate persons to register through financial rewards for donation. Second, the positive psychosocial effects of donation as described earlier have been successfully used by many donor centers and registries as part of their recruitment strategies. In a setting with donor remuneration, these strategies could not be used anymore. Thus, the offer of remuneration could adversely affect both the willingness of those already on the registry to continue as well as the recruitment of new persons to the registries.

Effect on international exchange

The current system of international exchange is based on the willingness of all participating registries to adhere to a common set of standards and guidelines. These standards are informed by a common set of ethical, legal, and practical concerns. Remuneration also raises the concern that the donor who is paid may believe he or she has a lingering economic right if the unit is not used for the intended purpose. WMDA addresses this concern indirectly by requiring that a donation not be cryopreserved as a matter of practice. In the rare instances when a product is saved and not used for the intended patient, the uncertainty created by the potential of other uses when the product was sold for a specific use would be unacceptable. Variation in country ownership laws would create further uncertainty in international

exchange. If the WMDA were to adopt a standard that allows for use of a remunerated donor, those countries that prohibit remuneration or have standards that do not permit remuneration for safety or other reasons would need to screen out donors from countries that permit remuneration. This could create a 2-tiered system of registries and would complicate the current system of international exchange. The effect would be to reduce the potential pool of donors for patients in some countries and undermine the cooperation among the registries.

Recommendation

The price assigned to the value of human donation is literally the value of life, which cannot be expressed in monetary terms. Donor remuneration raises difficult ethical issues, has the potential to damage the public will to act altruistically, and may involve coercion and exploitation of donors. It may also place patients at increased risk, negatively affect local transplantation programs and international stem cell exchange, and may benefit some patients while disadvantaging others. These concerns have resulted in several national and regional registries as well as legislative and regulatory bodies worldwide to oppose remuneration for the donation of HSCs as well as organ and blood. The WMDA, therefore, concludes that remuneration for HSC donors is undesirable and may be deleterious to the international transplantation community of both patients and donors.

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