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The Potentially High Cost of a Free Clinical Trial - Commentary on When a Clinical Trial is the Only Option

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Despite the rarity of the disease in question and the patient's status as an undocumented immigrant, the primary ethical challenges in this case reflect complex phenomena that affect most medical care and clinical research in the United States (Taylor et al 2016). For the research ethics consultant, the most pressing of these issues are the financial and social barriers that limit access to medical care, divergent perspectives among members of the multidisciplinary care team, and the subtle power of the therapeutic misconception.

The appropriate use of BMT for many hematologic cancers, including myelofibrosis, remains a source of ethical debate because of its extraordinary financial cost, its intense and often protracted physical burden, and its relatively low survival rate (Experts in chronic myeloid leukemia 2013; Himmelstein DU, et al 2009). Nonetheless, the Hematology-Oncology team likely would have offered BMT soon after diagnosis if the patient had had comprehensive insurance or the personal wealth to fund the procedures and the life-long post-transplant drug regimen. If a related donor were not readily available, his physicians probably would have sought a non-related donor through the National Marrow Donor Program (<https://bethematch.org>). However, it appears that the team has not even mentioned BMT to the patient in the three weeks since admission, most probably because they understood the intervention to be financially inaccessible to him. Instead, the Palliative Care service has been consulted for a shift to comfort measures and home hospice care.

There is general consensus that physicians have no ethical obligation to *offer* treatments of limited effectiveness - including available clinical trials, especially when such intervention also imposes high physical burden, likelihood of suffering, and financial costs (The American Thoracic Society ad hoc Committee on Futile and Potentially Inappropriate Care 2015). However, following a life-threatening diagnosis, it is also best practice for physicians to talk with the patient and family about goals of care and recommended options, including why some interventions are not recommended or are not truly options (Bernacki RE and Block SD 2014). While the team's initial decision not to discuss BMT may have seemed like a compassionate response to the patient's insurmountable financial barriers to treatment, the discovery of the clinical trial and possible "free" treatment highlights the paternalism of that unilateral decision. Moreover, raising the possibility of a clinical trial with BMT at this late date would likely introduce the therapeutic misconception into the patient's assessment of

BMT's benefits and burdens: *Why would the team offer the possibility of BMT now if it they did not recommend it - surely entering the trial must be in my best interests.*

A central task for the research ethics consultant is to help the multidisciplinary members of the care team identify their common goals of care for this patient and how the clinical trial fits or does not fit within them. Up to this point, the financial inaccessibility of BMT has apparently helped to bridge the divergent professional perspectives of the multidisciplinary care team on the goals of care. Now, however, before raising the possibility of the study with the patient and his family, the multidisciplinary caregivers need to come to a common understanding of what is truly involved in the trial and whether it changes their previous assessment.

Over the past two decades, ethicists and regulators have increasingly emphasized the need for clinical investigators to disclose the full financial costs of participating in a clinical trial as part of the study's informed consent process (US Department of Health and Human Services 1998; Wong Y-N et al 2016). Not only will such consideration be essential to the ethics of this study's enrollment process, the current care team needs to appreciate the significant expenses and logistical demands that the patient and his family will encounter in order even to be evaluated for eligibility. While the Hematology fellow appears to have resolved concerns about the costs of HLA testing through a private charity, many other expenses will need to be met before the patient can qualify for the trial. The research ethics consultant should encourage the team, especially the fellow advocating for the clinical trial, to identify these other likely financial and logistical hurdles, together with any possible sources of support or means to overcome them. Only then can a comprehensive calculation of benefits and burdens begin. For example, the team will need to consider and seek answers to the following set of questions:

- What costs would the patient, together with a required family caregiver and potential sibling donor, incur in traveling to the study site, as well as for housing, meals, and ground transportation during the study?
- Although the patient appears stable enough to be discharged for palliative care at home, will the 900-mile journey require expensive medical transport?
- If the patient should become significantly sicker while at the study hospital, what might it cost for other family members already in the US to be with him in his final days?
- If he should die during the study, what will it cost to transport his body for burial, either back to his US home or native country?
- If one of the siblings in Central America is the best match, does he or she have a passport? If not, how long will it take to get one, and at what cost?
 - How long will it take to get a medical visa for travel to the United States, and what costs will be incurred in that process, including application fees and travel to their country's US embassy for an interview?

- Can the sibling leave work and family for the time it may take to be evaluated for the study and, if suitable, donate marrow? If so, how much will he or she lose in unpaid wages?

Moreover, as undocumented immigrants who speak no English, the patient and his wife – and his potential donor sibling in Texas – are at higher risk for detection, detention, and even deportation if they travel long distance into an unfamiliar environment. Hospitals have no legal duty to report unauthorized immigrants, but the need to present identification in commercial and even private travel may result in the patient's interception outside the hospital. Not only would detention eliminate the possibility of the patient taking part in the study, it would likely interrupt even his basic palliative care. An investigation by immigration officials would also likely reveal any other members of the patient's family not authorized to be in the US. The cost of legal representation, if available, could be staggering.

Once the medical team has clarified its recommendations about the trial and can present them in practical terms of benefits, costs, and burdens, the patient and his family need to be brought into the discussion. Not only does shared decision making respect the patient's individual autonomy, the patient's and family's own knowledge of their personal resources, limitations, and values are essential elements in the larger assessment of available treatment options. And even if ultimately the medical team is unwilling to recommend the BMT trial, both they and the patient and his family may find comfort in knowing they have evaluated and rejected that option, and go home reassured that their plan for hospice care is the best choice from among everything available (The American Thoracic Society ad hoc Committee on Futile and Potentially Inappropriate Care 2015, Bernacki RE and Block SD 2014).

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