OPTN/UNOS Ethics Committee

Report to the Board June 28-29, 2011

Chair, Michael E. Shapiro, MD, FACS Vice-Chair, Alexandra Glazier, MPH, JD





2010-11 Activities Update

- April 10-11, 2011 The Committee held a joint inperson meeting with the Ad Hoc International Relations Committee to review and substantially revise Policy 6.0 regarding non-resident alien transplantation, international organ sharing arrangements, and the current 5% non-resident alien rule.
 - Proposed modifications to data collection forms; and
 - Proposed modifications to the text of Policy 6.0.



Ethical issues pertaining to transplantation of non-US recipients (Policy 6.0)

- Definitions
- OPTN and UNOS positions re: Declaration of Istanbul
- Appropriate Allocation algorithms under NOTA and the Final Rule



Ethical Issues - Definitions

- Policy 6.0 defines US citizens, resident aliens and non-resident aliens
- None of these definitions as stated include un-documented US residents
- Un-documented may be largest category of non-citizens receiving transplants in US, but currently no way to capture those data.





Ethical Issues – Declaration of Istanbul

- OPTN has accepted definition that travel for transplantation becomes transplant tourism:
- "If the resources (organs, professionals and transplant centers) devoted to providing transplants to patients from outside a country undermine the country's ability to provide transplant services for its own population."



Ethical Issues – Istanbul, cont'd

- UNOS has adopted *Principles*, including:
- 5b: treatment of patients from outside the country or jurisdiction is only acceptable if it does not undermine a country's ability to provide transplant services for its own population.
- 6a: Prohibitions on these practices should include a ban on all types of advertising (including electronic and print media), soliciting or brokering for the purpose of transplant commercialism, organ trafficking or transplant tourism;

OPTN



Ethical Issues – NOTA, Final Rule

Some have stated that NOTA and Final Rule require OPTN to base allocation policy solely on "established medical criteria."

But:

- Both require OPTN to develop policies for "equitable allocation of cadaveric organs" (FR 121.4(1))
- US residents (citizens, permanent residents, undocumented residents) contribute to the donor pool, whereas non-residents do not, thus raising questions of equitable allocation and justice.



Ethics – NOTA, FR, cont'd

- FR 121.4(3)(iv): "OPTN...shall be responsible for developing...reform of allocation policies based on assessment of their cumulative effect on socioeconomic inequities"
- As many of those who travel to the US for transplantation are not representative of the socioeconomic status of either US residents waiting, or those in their own country in need of organs, this fosters further socioeconomic inequity.





Current Committee Efforts

- Uncontrolled DCD/Rapid Organ Recovery
 - The committee has discussed this as a significant opportunity to enlarge the donor pool. A subcommittee has been formed to prepare a position paper for consideration.
- Kidney Allocation
 - The Committee regularly reviews the progress of the kidney allocation system development and believes strongly that the Kidney Committee should begin considering ways to address geographic disparities in allocation.



Ethics Committee

- Next meeting date will be in September 2011
- New leadership:
 - Chair, Alexandra Glazier, MPH, JD, General Counsel, NEOB
 - Vice-Chair, Peter Reese, MD, University of Pennsylvania



Thank You

The opportunity to Chair the Ethics Committee for the past three years has been an incredibly challenging, yet educational, enlightening and rewarding experience.

