

Feb 25, 2019

The TTS China Relations Committee was formulated for two purposes:

- 1) Analyze the current situation of solid organ transplantation in China in order to inform TTS leadership and facilitate TTS-China relations
- 2) Provide guidance to pharma working in China to optimize sound scientific and ethical clinical trials

The committee members are Nancy Ascher, Marcelo Cantarovich, John Fung, Peter Stock and JP Mongeau. This morning we had a conference call with the above members and Alan Leichtman, Jack Kalbfleisch, Francis Delmonico and Haibo Wang. We specifically invited Haibo Wang as Director of the COTRS (Chinese Organ Transplant Response System) to speak to the group and asked Jack to speak to the modeling used in the Lavee preprint that has been widely distributed in which the authors accuse China of a deliberate falsification of donor/transplant data to obscure an alleged ongoing use of executed prisoners of conscience.

- Haibo Wang explained that COTRS originally was established as a vehicle to distribute deceased donor organs and modeled after the US UNOS system. Every person in China is assigned a unique identification number and every deceased donor is recorded. Live donor transplant does not get automatically reported to COTRS. A question was posed as to the validity of the >6000 voluntary deceased donors now being achieved in China. The response by Dr. Wang was to assure the identity of each donor being ascertained by the person's unique identification number. However the four transplant registries (kidney, liver heart and lung) fall under the jurisdiction of COTRS-so COTRS has access the data from both deceased and live solid organ transplantation in China. The current registries China grew out of a liver transplant registry begun by Wang and ST Fan in Hong Kong and a kidney registry that began in Beijing at a military hospital.
- The Red Cross may or may not be informed of specific donor depending on the local province politics. As a result, the number of donors recorded by the Red Cross may be different from that recorded by COTRS. HW denies that the Red Cross "pays for" deceased donors; he did not deny that the Red Cross pays funeral expenses for deceased donors.
- COTRS reports donor and distribution data annually to the Ministry; inconsistencies are noted and reported on a center basis(eg distribution of an organ to a patient preceding the listing of that patient). Haibo could not speak to the protocol used by the Ministry to investigate transgressions reported. (A request has been made by the TTS China Committee to Minister Ma to speak with the committee and address this question.
- HW was asked whether it was illegal in China to transplant foreign nationals. He stated that if an individual had a Chinese identification number(see above), but then moved away and became a citizen of another country, the individual would be obligated to let Chinese officials know. Further, it was stated that a given transplant center would not be able to determine dual citizenship and would assume that a patient born in China was a citizen in good standing. In addition "compassionate" transplants could be



performed in a foreign national in China with “special” permission from the Ministry of Health.

- JK informed the group that the fact that the number of donors in China fits a binomial distribution neither proves or disproves falsification of data. He went on further to say that the rate of growth in China cannot be compared to the other centers reporting to ONT because most countries have stable or slowly growing donor numbers. He went on to say that the analysis based on R squared in Appendix 1 is faulty in that a country like China that has a growing transplant program will always have a larger R squared than the other countries which are nearly in steady state or growing less consistently. Further, simulations show that the R squared observed for China is no larger than would be expected by chance. Thus, the analysis in appendix 1 does not show that the agreement with the binomial model is too close as the authors claim.

The committee found this discussion very fruitful in increasing our understanding of the Chinese system. The number of deceased donors in China is credible and systems are in place for sustaining the reform that is underway. There are further questions which are important for the Red Cross to answer. We also are eager to hear from the Minister as to how he addresses potential transgressions in the system and whether there are objective criteria for “compassionate” transplants. The committee does not support the claims of the Lavee preprint that the numbers of deceased donors in China over the past three years have been deliberately manufactured.