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RE: Request for Information Regarding Development and Operation of a  
Transplantation Sentinel Network (TSN)

The American Academy of Orthopaedic Surgeons (AAOS/Academy), representing over 17,000 Board certified orthopaedic surgeons, welcomes the opportunity to offer comments regarding the development and operation of the Transplantation Sentinel Network. It is imperative that a national network is developed and implemented to improve the safety of patients who are recipients of organs and tissues. A national system will assist in the detection and prevention of disease transmission from organs and tissue allografts recovered for transplantation.

The AAOS has been an active partner throughout the development of the Transplantation Transmission Sentinel Network (TTSN) and initiation of the pilot program. The AAOS is committed to aiding in the safe transplantation of tissue allografts. In order for this to occur, a tracking system should be in place to decrease risks for transmitting infections to recipients, through actions such as the prompt recall of contaminated tissue. Early recognition of disease transmission from an organ or tissue is paramount in the prevention of other recipients potentially receiving tissue from that donor. Real time recognition and communication is a key element of a successful network.

Additional benefits may be realized from the successful operation of the national Transplantation Sentinel Network. It is possible for the Network to function indirectly as an outcome database for successful allograft tissue use based on adverse event/reaction/complication reporting. The Academy supports the implementation of a system that will provide valuable information, while protecting our patients.

The AAOS believes that the following elements are critical to the development and operation of the Transplantation Sentinel Network:

- Transitioning from the Transplantation Transmission Sentinel Network (TTSN) prototype to full production
- Standardization and compatibility
- Reporting criteria
- System operation and infrastructure management

- Privacy and security for patient health information

### **Transition of Transplantation Transmission Sentinel Network (TTSN) Prototype to Full Production**

The successful transition of the TTSN prototype to a fully functioning system will take thoughtful planning. Key factors in the system's transition include:

- Considering the time allotted to the start-up, preparation, and implementation phases of the TTSN project;
- Reviewing of the final report of TTSN project;
- Maintaining patient safety as the primary goal;
- Identifying and securing adequate long term funding.

The overall goal of TTSN was to improve patient safety for organ and tissue recipients and should remain the focus during the implementation of expansion of the system. It took approximately three years to establish a universal TTSN donor number system containing a web-based network for login for organs and transplantable tissues. The pilot allowed for ample time to work out glitches and unanswered questions and familiarize participants with the system, which may work to the advantage of the TSN system. A final report containing pertinent information about the pilot project has yet to be released from the United Network for Organ Sharing (UNOS), but would be very helpful to use during the planning of TSN. In light of the importance of this system, adequate funding mechanisms should be identified and secured in order to sustain it. A system such as this one will be extremely beneficial to enhancing safe use of allografts and other tissues, and it would be of great detriment to our patients if it were unable to be sustained due to inadequate funding. The TTSN pilot project displayed a successful and functional system. As such, it would be a judicious use of resources to leverage most, if not all, components of the TTSN system into the TSN.

### **Standardization and Compatibility**

Existing data sources must be able to interface and link every piece of tissue to a universal donor number recognized by vendors, tissue banks, suppliers, distributors, and end users. Whether accomplished electronically or manually, the real-time link between these data sources will greatly enhance the systems ability to identify tissue from an affected donor and prevent its transplantation. Retrospectively, this interoperability will provide a foundation for outcomes research that will contribute to the continuous quality improvement of tissue transplantation.

### **Reporting Criteria**

It is imperative that uniform, confidentially reported data be incorporated into the system. Identifying specific conditions of organ transplant recipients, such as hepatitis B, hepatitis C and HIV status should be required, in addition to the results of initial and follow-up screening tests post transplantation. UNOS informally requests specified information one year post-transplant, but this information is not linked to

universal donor information. Mandatory reporting could further enhance safety by facilitating an almost immediate quarantine of potentially contaminated tissues until additional testing can identify the source of the contamination. Uniformity, accuracy and timeliness in reporting of this information is imperative to the system functioning as intended.

There is significant under-reporting of adverse reactions due to many factors. Part C of the TTSN pilot project included a notification system for potential adverse events, which provided trace-back and trace-forward mechanisms for event identification. Efforts should be made to increase the voluntary reporting of data when tissue-related complications occur. It is our hope that the TSN system will help reduce the under reporting of potential adverse outcomes.

### **System Operation and Infrastructure Management**

In order to ensure that the TSN system's infrastructure is managed and operated efficiently, key features include proper training, effective oversight, and appropriate log-in of information.

The TSN must identify and train staff that will be responsible for proper system operation. Staff should be trained to recognize and correct errors in the system, identify triggers for quarantine of infected or suspected tissue, and empowered to provide real-time feedback and support to system users. Mechanisms exist within the FDA, under the MedWatch program, to capture adverse events of tissue within fifteen days of the event. The TSN system should not intend to take the place of the current reporting system. Ideally, the systems should be configured to share information.

In order for the TSN system to prevent recipient adverse outcomes, the hospital or surgical center must actively participate in tracking the use of allograft tissue, prior to implantation. Part B of the TTSN pilot project had the ability to track the disposition of any implanted allograft, and required data collected to include graft ID, graft type, procedure date and type, recipient demographics, and surgeon last and first name. However, there were situations during the pilot where usage of an allograft was logged into the web site after the surgical case, circumventing the preventive potential of the system. Major strides have been made by use of Joint Commission's Universal Protocol related to marking patients to prevent wrong site surgical procedures prior to having the patient brought into the room, and time-out prior to the start of the procedure or incision. We recommend incorporating the use of the TSN system into the Universal Protocol for cases involving tissue in order to maximize the prevention of adverse events.

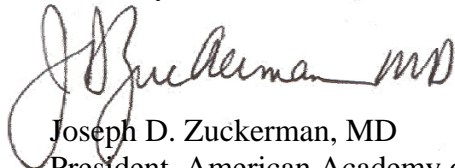
### **Privacy and Security for Patient Health Information**

Privacy and security of patient health information is an extremely important factor for the proper functioning of this system. Patients must feel that their information will be protected through this shared network system. Also, the system should have safe guards in place that ensure that the correct information is entered into the correct

patient's record. Security measures should be implemented to make sure that patient information is accessible yet protected.

The Academy has been a partner and supporter of the TTSN project and hopes for this to continue with TSN. The safety of our patients remains a predominant focus. There is tremendous need for a national system that assists in the detection and prevention of disease transmission from organs and tissue allografts recovered for transplantation. The successful implementation and operation of a uniform system that allows for the sharing of pertinent organ and tissue information is a great asset. It is our hope that this system will prevent countless patients from receiving infected tissue. AAOS looks forward to assisting with the development and implementation of the Transplantation Sentinel Network.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Zuckerman MD". The signature is fluid and cursive, with the "MD" written in a slightly different style at the end.

Joseph D. Zuckerman, MD  
President, American Academy of Orthopaedic Surgeons