



October 31, 2011

The Honorable Donald M. Berwick, M.D., M.P.P
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS Global Immunization Policy - Unintended Consequences and Safety Concerns for Organ Transplant Recipients

Dear Dr. Berwick:

On behalf of the American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS), we write to express our significant concerns regarding the CMS global immunization policy (as expressed in Specifications Manual for National Hospital Inpatient Quality Measures) and possible unintended consequences for organ transplant patients. Our two societies represent the vast majority of surgeons, physicians, and other professionals involved in organ transplantation throughout the nation, and in an effort to protect the health and welfare of this vulnerable population, we urge you to reassess the potential for adverse impact on our patients before finalizing policy.

The Infectious Diseases Community of Practice of the American Society of Transplantation (ID-COP of AST) strongly supports immunizations as a protective measure for transplant recipients. However, our reading of the new policy is that every inpatient will be required to receive influenza and pneumococcal vaccinations regardless of timing relative to transplantation. While the mandate exempts patients during their transplant hospitalization it makes no allowance for withholding vaccination if a recent transplant recipient is discharged and then readmitted to the hospital. For a fresh transplant recipient, the impact of potent immunosuppression in the peritransplant period makes it unlikely that therapeutic benefit will be obtained. In addition, this is a vulnerable period with the greatest risk of acute rejection. Accordingly we are concerned that a temporal association between vaccination and rejection may be made even if a causal relationship is absent. A bias already exists in the community against immune stimulation during the period of greatest risk of acute rejection; a temporal association

with vaccination will only harm efforts to immunize this population later when they are more likely to achieve benefit.

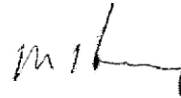
After intense review of literature, the ID-COP of AST recently published recommendations regarding influenza vaccinations for the transplant population [Kumar et al AJT 2011]. The recommendations are to withhold immunization during the first three months after transplantation. Due to the seasonal nature of influenza risk, consideration can be given to vaccinating as early as one month after transplant during periods of high influenza activity vaccination.

Our societies and the transplant community remain concerned that the CMS policy, as presently drafted, offers little benefit with the potential for significant harm. Thus, we respectfully request that CMS exempt transplant recipients from any final Global Immunizations policy. We will be happy to provide additional support for our request or to assist you in any way possible as you consider this important decision.

Sincerely,



Robert S. Gaston, MD
AST President



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ASTS President

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