Initial Analyses of Suspected Pump Thrombosis

In view of recent institutional concerns about a possibly increased incidence of HeartMate II pump exchanges for suspected pump thrombosis, INTERMACS has performed analyses of this event as well as patient survival with the HeartMate II device in our database. The date of May 1, 2011 (see figures below) was chosen by the FDA. Further analyses are underway to examine factors contributing to the relatively small increase in HMII pump exchanges in recent years, including such factors as changes in pump design, anticoagulation strategies, and patient-related issues. While detailed analyses are underway, we wanted to make available to our participating hospitals these initial analyses.

Stratified actuarial curves depicting freedom from HeartMate II pump exchange attributable to pump thrombosis. Note the significant increase in events after May, 2011, but the magnitude of increase was relatively small.

Stratified actuarial curves depicting survival in patients receiving a HeartMate II pump. Notice the essentially identical survival in the two cohorts.