ASTS President
A. Osama Gaber, MD, FACS
on
SRTR Task 5 Initiative

VIRTUAL PRESENTATION TO THE SRTR TASK 5 STEERING COMMITTEE
THURSDAY, SEPTEMBER 23, 2021 – 4:00-5:30 P.M.
• ASTS is supportive of maintaining data transparency to ensure patient safety and to foster innovation and research.

• ASTS is committed to advocating for a patient focused system approach which incentivizes transplantation by reducing risk-averse behavior by transplant programs and promotes innovation.

• ASTS welcomes the opportunity to be engaged in envisioning the future for data science and the Scientific Registry
Task 5: ASTS Perspective

ASTS recognizes that the Final Rule requires disclosure of:

- Risk-adjusted probabilities of receiving a transplant or dying while awaiting a transplant,
- Risk-adjusted graft and patient survival following the transplant, and
- Risk-adjusted overall survival following listing for such intervals as the Secretary shall prescribe.
• ASTS believes that transplant data should be modernized without increasing the burden of data collection

• ASTS believes that SRTR should alter its collection, analysis and reporting of data to become a resource for advancing patient safety, quality, research, and innovation rather than being mainly focused on support of regulatory functions

• ASTS believes that the current data reporting structure has problems that need to be addressed in the future planning for the SRTR:
  • risk adjustment is incomplete and promotes risk aversion,
  • star ratings promote a competitive system that prevents collaboration,
  • the current Provider Specific Reports require transplant programs to achieve an increasing and unpredictable survival metric
Regulatory Metrics should be pre-determined and noncompetitive and achieve patient safety

- **Goal:** To focus patient attention on the survival benefits of transplantation and to remove the disincentives to transplantation inherent in the current star ratings system.
- Centers will achieve a predetermined, fixed standard rather than being ranked according to a very narrow range of difference in survival rates for a cohort of patients transplanted between 1.5 - 3.5 years ago.
  - **Bone Marrow Transplant** programs are FACT accredited and meet a pre-determined standard.
  - **HLA labs** are accredited, not ranked.
ASTS Metrics
Recommendation
#1
Regulatory Metrics should be predetermined, noncompetitive and achieve patient safety

Regulatory metrics

• The target metrics for graft survival and patient survival should be fixed based on survival with the alternative therapy (dialysis, VAD, or best supportive care for liver/lung): kidney transplant one-year patient survival should be chosen with reference to the 89-90% 1 year hemodialysis survival for mean age of kidney transplant recipient in US (USRDS).

• Risk adjustment could be addressed by performing a second, risk adjusted assessment of programs performing below the standard, to allow for programs that transplant a disproportionate number of high-risk recipients or use a significant number of higher risk organs. Variables selected for risk adjustment should be precise (such as age, DCD) and these should be selected using a transparent process.

• Transplant programs should not be graded on a system which automatically cites the lowest cohort of programs, as this discourages cooperation and collaboration between centers, which disadvantages patients.
The STAR rating system should be eliminated

- The star system exaggerates marginal differences in outcomes, misleading patients in their waitlist choices and payers in their network determinations. Sixty-three (63%) of kidney transplant centers with 100% risk adjusted one-year patient and graft survival are designated as having only three (out of five) stars on the survival metric.

- The star system encourages patients to choose transplant programs on the basis of rankings that are likely to change significantly by the time the patient is transplanted. (Schold et al AJT 2018).
The STAR rating system is misleading to patients and payers and should be eliminated.

- The five-star rating criteria encourage behaviors that are not in the best interests of patients:
  - Very high one-year outcome criteria encourages risk adverse recipient and organ selection, decreasing access to transplant.
  - Transplant rate criteria encourage transplant programs to only list patients with high enough priority to be transplanted.
  - Waitlist mortality encourages transplant programs to refrain from including sicker but still transplantable candidates from their waitlists.
The STAR rating system is misleading to patients and payers and should be eliminated....

• The star system results in exclusion of transplant programs from payer networks based on marginal outcomes differences and spurious changes in ranking.

• The star rating is based on data that is from several years prior to the current listing, thus may not apply to current listing.
An increased focus on ensuring equity in access to transplantation

The current metric “people transplanted per one hundred years of waiting” is not easily understood or sufficiently concrete to serve as a useful tool for those considering transplantation as a treatment option.

ASTS agrees with the joint ASN/NKF Joint Task Force recommendation (March 2021) to remove the race modifier in the calculation of eGFR and is supportive of the current OPTN request for comment on this topic.

ASTS recommends a joint SRTR, OPTN, and society working group to develop a quality improvement project, including increasing access to the waiting list.

ASTS recommends revision of the public information available to prospective recipients regarding transplant candidate listing criteria (age, BMI, etc…) and types of donors the center accepts (living donor, DCD, HCV+).
Public disclosure of more user-friendly waitlist and other access information

Allocation models which create a sex-based disparity in access to transplantation resulting in a higher waitlist mortality for females, such as MELD-Na, should be revised.

The metric “getting a deceased donor transplant faster” likewise is not useful as a decision tool in light of the numerous factors that may determine waitlist time for any individual patient.

SRTR should work closely with patient organizations to revise the public information available with respect to waitlist times.

Transplant center waitlist criteria and other information regarding special features of each program should be made easily accessible in the Summary pages of the PSR. For example, whether the transplant program uses DCD organs, HCV/HIV positive donors/ high KDPI organs/ do kidney swaps/transplant people above 70 yrs./BMI >40.

ASTS also recommends:
• Better data by eliminating what is unnecessary; add new information that it beneficial for the field.

• Transform the SRTR into a quality improvement and innovation driver, and consider types and sources of data, linkage of data to other national databases, and provide patient-facing interfaces that address patient primary concerns.

• SRTR conversation should be done in context of the larger picture of transplant data sciences and with all the relevant stakeholders.