

## Saving and improving lives with transplantation.

Submitted via email: srtr@srtr.org Regarding: Task 5 Public Comment

May 2, 2022

Jon Snyder, PhD Director Scientific Registry of Transplant Recipients 701 Park Avenue, Suite S-4.100 Minneapolis, MN 55415

Dear Dr. Snyder:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have the opportunity to respond to the Scientific Registry of Transplant Recipients (SRTR) solicitation of comments on the Task 5 Initiative. We understand that the goal of this initiative is to "identify metrics to assess national transplantation system performance and support informed decision-making by critical audiences."

Our recommendations regarding SRTR metrics were provided to the SRTR in oral comments on September 23, 2021<sup>1</sup> and are available <u>here</u>. However, since that time, there have been important developments that we believe warrant consideration. In particular:

- The Centers for Medicare and Medicaid Services (CMS) issued a Request for Information (RFI) soliciting information on changes that should be made to the Transplant Center Conditions of Participation (CoPs), especially with respect to metrics and transparency of information provided to patients;
- The Health Resources and Services Administration (HRSA) also issued an RFI soliciting comments on potential changes in the role and responsibilities of the Organ Procurement and Transplantation Network (OPTN) (including potential changes in the OPTN's data collection and management systems and the need for increased focus on transparency with respect to information provided to patients); and

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<sup>&</sup>lt;sup>1</sup> See ASTS virtual presentation to the SRTR Task 5 Steering Committee, Thursday, September 23, 2021 (<a href="https://asts.org/docs/default-source/regulatory/asts-presentation-to-srtr-task5-steering-committee-september-23-2021.pdf?sfvrsn=500a47d3\_2">https://asts.org/docs/default-source/regulatory/asts-presentation-to-srtr-task5-steering-committee-september-23-2021.pdf?sfvrsn=500a47d3\_2</a>).

The National Academies of Sciences, Engineering and Medicine (NASEM) issued a
comprehensive report setting forth a blueprint for improvements in the national transplantation
system (including, among other things, the need to establish national transplantation goals and
a "dashboard" to chart progress towards these goals).

While we understand that Task 5 charges the SRTR with the development of system metrics, we strongly concur with the NASEM Report recommendation that metrics should be formulated to track progress toward specified goals, and the establishment and prioritization of the system goals should precede efforts to design metrics: Otherwise, the exercise risks becoming "measurement for measurement's sake." We further believe that the establishment and prioritization of goals is a task that should involve agencies beyond HRSA, including most notably CMS, but also including the FDA, NIH, and other offices within HHS. The establishment of national goals—and especially the ranking of priorities—is not as easy an exercise as it might at first appear, since there are inevitably tradeoffs and tensions among various goals. For example, there are potential tensions between the goal of maintaining and improving transplant outcomes and increasing utilization of hard to place organs; between increasing transparency and expediting decision making; and between increasing organ sharing and lowering the cost of transplantation. In our view, the balancing of priorities among various important system goals should precede the establishment of metrics to measure progress toward those goals. For this reason, we urge SRTR to actively involve other agencies with jurisdiction over transplantation in the establishment of goals and the weighting of priorities as a precursor to establishing the metrics called for by the Task 5 initiative.

Because of the complexity of the transplantation process, we also request that SRTR consider the potential unintentional consequences of any metrics that emerge as a result of the Task 5 initiative. In the field of transplantation, it has been shown that metrics drive behavior, and, in fact, they are often intended to do so. However, behavior changes incentivized by new metrics may have consequences that were not intended, and we believe that any recommendation to establish new metrics should be accompanied by a "SWOT analysis" that identifies potential unintended consequences.

More generally, we believe that new and continued data collection activities moving forward should comply with the following principles:

- Data collection should be clearly tied to, and necessary for the achievement of, a clearly stated goal or objective that is one of the National Transplantation Goals.
- New data collection should be authorized only if the data is unavailable from any existing data source.
- The appropriate audience for the data should be clearly identified and consulted about the utility of the proposed data collection before data collection is instituted.
- How data is used should also be considered and any new metrics should be classified as to their purpose. For instance, will the data be compared to other data on a national or local level, or by center to center? Will the data be presented on a curve or by using a minimal baseline? We believe any patient facing public information should be distinguished from program quality metrics.
- The potential inadvertent repercussions of data use and dissemination should be thoroughly considered in advance.
- The data collection administrative burden on transplant centers should not be increased: If additional data elements are to be collected, an effort should be made to reduce or eliminate

other data collection requirements that may be unnecessary, obsolete, or not tied to a national transplant system goal.

We appreciate the opportunity to provide input to the SRTR with respect to the Task 5 initiative and look forward to participating in the Consensus Conference this summer.

Sincerely yours,

A. Osama Gaber, MD, FACS

President, American Society of Transplant Surgeons