Ad Hoc Committee on Program Specific Reports

Board of Directors Meeting
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OPTN

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Background

- A consensus conference was held on February 13-15, 2012.
- The purpose of the conference was to discuss the methods used by the SRTR in the performance assessment of solid-organ transplant programs and to make recommendations for improvements.
- Participants included 115 attendees from transplant programs, the SRTR, the OPTN, CMS, and HRSA.
- Ad Hoc Committee was formed.

Ad Hoc Committee Members

Jack Lake, MD (Chair)	John Roberts, MD
Sandy Feng, MD, PhD	Tom Gonwa, MD
Ken Andreoni, MD	Larry Hunsicker, MD
Robert Merion, MD	Jennifer Milton, RN, BSN, MBA
Ron Potts, MD	Thomas Hamilton (CMS)
Karen Tritz (CMS)	Christopher McLaughlin (HRSA)
Robert Walsh (HRSA)	Monica Lin, PhD (HRSA)
Bertram L. Kasiske, MD, FACP (SRTR)	Jon Snyder, PhD, MS (SRTR)
Nicholas Salkowski, PhD (HRSA)	David Zaun, MS (SRTR)
Tabitha Leighton (SRTR)	Erick Edwards, PhD (UNOS)

Subgroup Tasks

Develop exclusionary criteria for PSRs based on patient's inclusion in a research protocol.

Should there be standard risk patient profiles that the PSR should be based upon?

CUSUM or similar techniques - How can these be used by the MPSC and centers to gauge improvement?

How can donor risk be better taken into account?

Develop exclusionary criteria for PSRs based on patient's inclusion in a research protocol.

- To receive an exception for experimental protocol, there has to be a true research protocol.
- The experimental protocol would need to pursue all the current criteria that would be involved in a government-registered clinical trial.

Develop exclusionary criteria for PSRs based on patient's inclusion in a research protocol.

- A control group that clearly matches all the exclusion criteria would also be required.
- All results must be recorded.
- Additionally, an MPSC subcommittee would have to determine whether the experimental protocol met scientific protocol.

Should there be standard risk patient profiles that the PSR should be based upon?

- There was little support for using a standard risk patient profile.
- There was support for allowing the centers to define which patients are high-risk outside of the criteria currently collected for the PSRs.
- The Subcommittee discussed a pilot program for the self-identification of high risk patients, but this option requires more discussion and is not yet a formal recommendation.

CUSUM (Cumulative Sum Control Chart) or similar techniques - How can these be used by the MPSC and centers to gauge improvement?

Currently, PSRs provide an average performance over a two-and-a-half year cohort but don't indicate whether performance is getting better or worse.

During the consensus conference there was strong support for the development of CUSUM reporting tools. Over the last year, the SRTR has worked closely with HRSA and developed a number of CUSUM options.

CUSUM Options

The static, semi-annual CUSUM chart is the least resource-intensive option. It would be generated every six months and show the previous three years of a program's experience.

A more resource-intensive option includes SRTR hosting the software, and allowing centers to download it for free. The programming script would produce CUSUMs based on data provided by SRTR, and the data could potentially be updated by the centers. A similar option would produce scripts every month from the centers' own data files

CUSUM Options

Ultimately, HRSA and SRTR decided on the monthly, static report option. The same standard risk adjustment models currently used in the six-month PSR cycles will underlie the CUSUMs. The risk adjustment models will not be updated every month, but the CUSUMs will be based on the most recent OPTN data each month. This option was chosen based on the quickness with which it can be implemented, and the relatively low resource requirement

CUSUM or similar techniques - How can these be used by the MPSC and centers to gauge improvement?

- The Committee's supports the static, monthly CUSUM report option. The reports will only be used and seen by the transplant centers, unless the centers choose to release the reports externally.
- The CUSUMs would be hosted on SRTR servers, and the transplant centers can log in and view the new monthly report, as well as all the past reports.

How can donor risk be better taken into account?

The assessment of donor risk is a technical issue that is already being addressed by SRTR within the context of updating the organ-specific PSR models.

There was some discussion regarding the potential to use certain data elements on DonorNet for the risk adjustment models.

How can donor risk be better taken into account?

The Committee stressed that evaluating the statistical models at regular intervals is vital. SRTR currently evaluates each organ-specific model every three years. The reevaluation should include clinically important interactions such as cold time and donor age.

Although the Committee decided not to pursue the standard risk profile for patients, it might be worthwhile to consider a standard risk profile for donors to remove the disincentive of using expanded criteria donors.

Questions