SRTR Technical Advisory Committee (STAC) Report to UNOS/OPTN Board

November 16, 2009

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Chair, STAC Committee

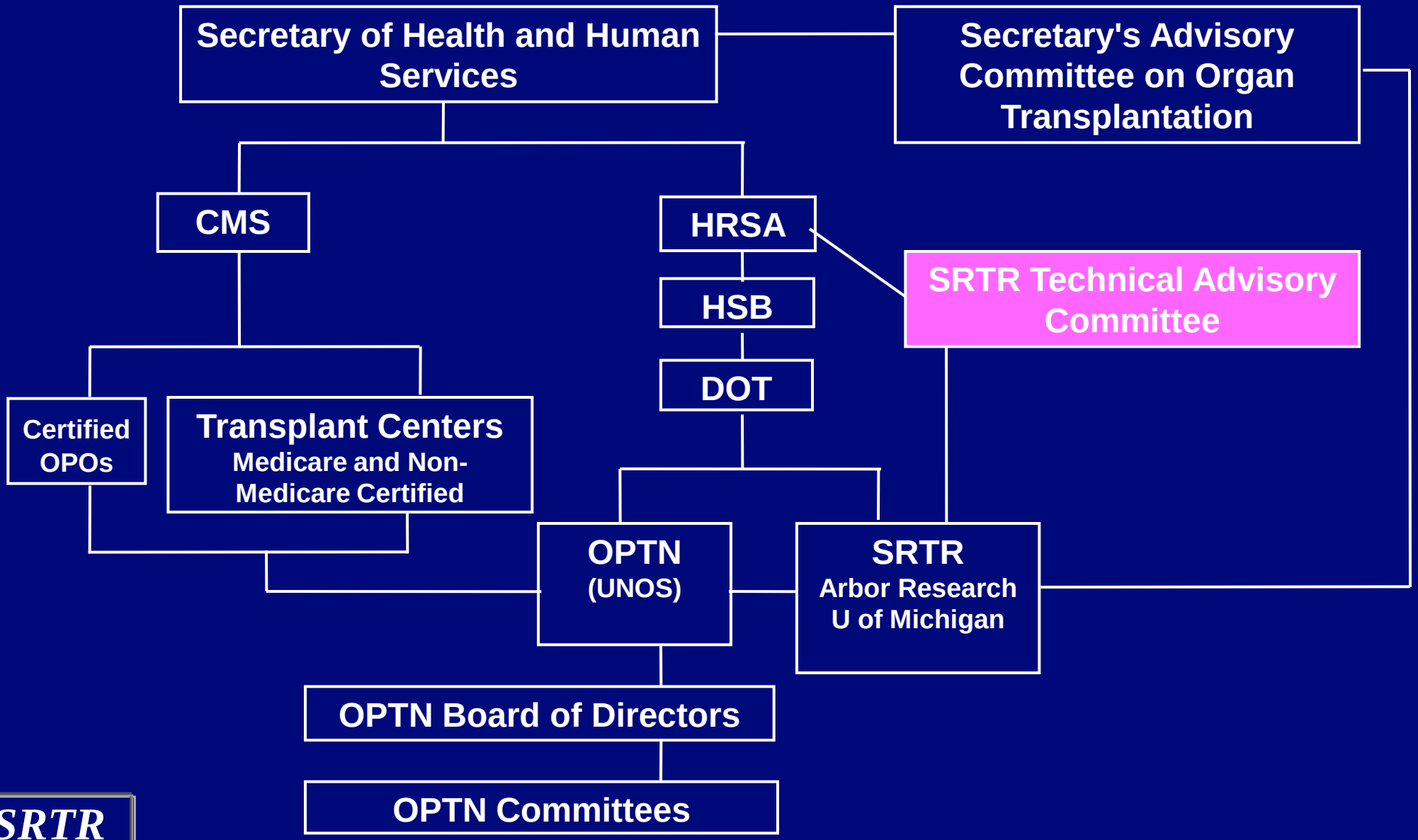
SRTR and OPTN: Complementary Roles

	SRTR	OPTN
Mission	Research / Policy Evaluation	Organ Allocation / Policy Development
Data Responsibilities	Inferential Analyses / Simulation Modeling	Data Collection / Descriptive Analyses
Contractor	Arbor Research/ University of Michigan	United Network for Organ Sharing

Data quality and scope: cooperative

SRTR

Key Players in the National Solid Organ Transplant System



SRTR

What is the role of STAC?

- Guide and review the research activities and OPTN committee requests of the SRTR
- Guide and review the publications by the SRTR and joint publications by OPTN and SRTR
- Provide scientific guidance and support to the OPTN and the DHHS, including the Secretary's Advisory Committee on Organ Transplantation (ACOT)

STAC Charter

- **STAC shall advise the SRTR staff, the joint OPTN Policy Oversight Committee, the OPTN Board of Directors and the various committees, sub-committees and working groups, and the DHHS on issues that affect:**
  - **Methodologies needed to support functions of SRTR**
  - **Research conducted by SRTR**
  - **Objective, design, and methods for research projects**
  - **Methods, content, and format of SRTR reports, Annual reports, reports to Congress, etc**
  - **New areas of research**
  - **Research reports and articles submitted to peer reviewed journals**

Who is STAC?

- They are not part of SRTR

They are 8-10 selected members who are:

- Representatives with qualifications in the areas of clinical, statistical, and/or epidemiological research related to transplantation, multi-center data collection, quality control, and utilization and biostatistics
- Clinicians with training and experience in transplant issues dealing with the kidney, liver, heart, lung, and/or pancreas
- Representatives from relevant OPTN committees

STAC REVIEW OF SRTR METHODOLOGY FOR PROGRAM SPECIFIC REPORTS

Background:
Regular Review of SRTR Methodology

- The SRTR reviews every model during each 6 month cycle – all available data considered (and tested if appropriate)
- The OPTN committees are notified of any changes to the models and those changes are published on the SRTR web site

Background: Survival methodology used by SRTR

- Based on well-accepted standard survival methodology
- Reviewed by independent technical expert panel convened by HRSA in 2004
- Methodology published in peer-reviewed journals: NEJM, AJT, JASA, Biometrics
- Same statistical methods are accepted and have been employed by CMS for 15 years
- Methodology presented to and endorsed by SRTR SAC in April 2005
- Available online on SRTR website: “Technical methods for transplant programs”

S-TAC Review of PSR Methodology

- Recent public/transplant center/society concerns for methodology and use of program specific reports (PSR)
  - Use for “punitive” reasons rather than “remedial” or “improvement”
  - Interfering with innovative strategies
  - Accuracy of data
    - Concern for missing data and manipulation of data
  - Appropriateness of current data points used to calculate statistical outcomes
  - Appropriate methodology
- Request for review of SRTR methodology by STAC

STAC subcommittee

- **Sub-committee members:**
  - **STAC members:**
    - **Janis Orlowski, MD (Chair of sub-committee)**
    - **Robin Pierson, MD**
    - **David Glidden, PhD**
    - **Kim Olthoff, MD**
    - **Monica Lin, PhD (HRSA)**
    - **Chris McLaughlin (HRSA)**
    - **Leah Edwards, PhD (OPTN)**
  - **Outside consultants**
    - **Jesse Schold, PhD**

HRSA charge to STAC

- **HRSA requested that STAC conduct a review of the methodology used by SRTR to develop models in the program-specific reports (PSR), the statistical methods used to develop PSR models, and the limitation of the methods, focusing on:**
  1. **the completeness of follow-up and the extra ascertainment of death and graft failure from external data sources,**
  2. **the strategies for addressing incomplete data and subjective variables,**
  3. **the predictive powers of PSR models,**
  4. **the limitations of the current OPTN data collection, and**
  5. **recommendations for improvement to both the SRTR models and OPTN data collection and validation processes.**

STAC subcommittee tasks

- Review of concerns, comments, and communications from UNOS membership:
  - Societies
  - Transplant centers
  - Individuals
- Detailed review of current methodology
- Review of outside literature on current methodology
- Review of alternative methodology
- Review of other healthcare outcome metrics contexts where performance metrics are utilized

Outline of STAC response

1. Regular outside review of methodology
2. Use of PSR for performance improvement and quality assurance
3. Predictive value of methodology
4. Missing data and subjective variables
5. Effect on innovation
6. Public concerns

1. Regular Review

- **STAC recommends a regular review of the methodology by a multi disciplinary sub-committee which will send its recommendation to HRSA, OPTN and SRTR.**
- **This review should occur at least every five years, but no more than every three years unless there is a significant change in transplant practice.**

2. Performance Improvement (PI) and Minimum Standards Quality Assurance (QA)

- 2 major goals of PSR
  1. PI by programs
     - typically carried out by programs through self-governing activities
  2. Minimum standards QA by governing bodies
     - enforced by governing entities
- SRTR statistics are useful for triggering both types of review

2. Performance Improvement (PI) and Minimum Standards Quality Assurance (QA)

- **PSR use for PI**
  - **The review of programs for PI may include recommended program attributes and outcome benchmarks.**
  - **should identify high performance for the purpose of identifying best practices as well as low performance for internal review as well as OPTN/MPSC programmatic peer review for potential intervention**

2. Performance Improvement (PI) and Minimum Standards Quality Assurance (QA)

- **PSR use for QA**
  - **Should be based on a minimum standard for program attributes and outcome benchmarks.**
  - **This minimum standard needs to be defined by the transplant community including oversight agencies, transplant professionals, and patient advocates.**
    - **Failure to meet these standards should trigger a quality assurance review and may result in a site visit, review of mitigating factors, development of a detailed corrective action plan, and, if identified issues are not remediated may include appropriate levels of actions up to and including decertification.**
- **It is appropriate that minimum standards QA decisions should involve a smaller percentage of facilities than are involved in PI efforts**

2. Performance Improvement (PI) and Minimum Standards Quality Assurance (QA)

- **Review of current PSR methodology used by SRTR**
  - **Current regression methodology for PSR is appropriate and statistically sound**
  - **since methodology approaches are constantly in development and other approaches have been utilized in other health care contexts, these new approaches should inform program evaluation**
  - **alternative approaches should continue to be explored and ongoing studies performed to evaluate their strengths and weaknesses as well as potential differences in the identification of centers requiring QA and PI evaluations.**

2. Performance Improvement (PI) and Minimum Standards Quality Assurance (QA)

STAC Recommendations:

- **The current PSR should continue to be the standard for continuous PI**
- **The OPTN/MPSC should establish a minimum standard for program performance used for QA of all programs**
- **The minimum standards for QA thresholds using the PSR methodology should be different than for PI and needs to be defined by the OPTN and outside governing bodies**
  - **There should be a minimal threshold for quality assurance.**
  - **The review of performance would allow continuous PI opportunities for those programs performing below their peer group <u>but within the accepted minimum standards QA limits</u>.**

2. Performance Improvement (PI) and Minimum Standards Quality Assurance (QA)

- "Flagging" programs has conflicting goals
  - Goal 1: Don't flag a program if it has no problem
  - Goal 2: Flag every program with a problem
- Current flagging for MPSC review
  - Utilized by OPTN/MPSC to review programs as well as providing best practices for improvement.
  - Current flagging for MPSC is different for "small" vs "large" (>9 transplants) programs
  - Flagging for MPSC review is "stricter" than what is on PSR public site (one-tail vs. two-tail)
  - Concern that current criterion flags an excess number of programs

2. Performance Improvement (PI) and Minimum Standards Quality Assurance (QA)

STAC recommendations regarding flagging

- Center size should not determine likelihood of being "flagged" and reviewed for the same performance, therefore STAC endorses alternative methodology for flagging of small programs developed by SRTR and proposed to MPSC at the September 2008 meeting
  - O/E >2.5
  - Currently under review and being tested
- Suggest that SRTR compare fixed volume to fixed time as a method for flagging
- "Flagging" for QA should be different than MPSC trigger for review

2. Performance Improvement (PI) and Minimum Standards Quality Assurance (QA)

- We must determine flagging outcomes
  - Outside bodies are now using the flagging for purposes other than PI, prompting the need for a thorough review of the methodology.
  - OPTN should provide information on the specificity and sensitivity of flagging in their program reviews.
    - The membership is not aware of the outcomes of flagging
    - OPTN does not have data compiled between programs “flagged” and those found to require peer review
    - The OPTN needs to define and classify the outcomes and adverse actions (if any) resulting from the review prompted by the flagging.
  - OPTN, HRSA and CMS should develop minimum standards and metrics for outcomes recommended for QA versus those used for the continuous PI process which flag programs for special review and potential sanctions.

3. Predictive Power

- Predictive power is a consequence of available data rather than methodology used.
- The predictive power of the current model is modest as compared to some healthcare outcome metrics contexts where performance metrics are utilized.
  - Comparison to other healthcare models that have better predictive power, as well as others with similar predictive powers.
- Even with the additional inclusion of multiple clinical parameters (ie Medicare claims data) the predictive power of the model doesn't change markedly
  - 2 recent studies in the literature showing concordance index only increased at most by 0.05 with inclusion of 20 comorbid factors
  - Despite inclusion of many additional fields to the current model, the discriminatory power of the models for transplant recipients may never achieve a level by non-health statistical science standards.

3. Predictive Power

- The limitation of the predictive power must be acknowledged if the information is public and used for oversight or regulatory purposes.
  - The public should be educated that the model is substantially better than crude mortality or morbidity rates but may not account for all differences between patients and between programs
  - The relatively low predictive power of the analytic models used for PSR suggest that mitigating circumstances are more relevant to interpret, evaluate, and explain variances from expected outcomes, especially for low-volume programs.
    - Lower predictive power may be from lack of medical information, noise or other environmental, socioeconomic or patient specific factors that we do not understand or have access to at this time,
    - OR programs may be quite similar and therefore the methodology can't distinguish between them

3. Predictive Power

- STAC recommendations regarding further review and study to improve the predictive power of the model.
  - Validation study to compare continuous versus categorical levels for factors in risk adjustment.
  - Explore statistical techniques for incorporating continuous variables.
  - Need to determine the resources required to achieve improved predictive ability (increased data collection, cost)
  - Review factors used in the model which may be subjective in nature. Recommend either elimination of subjective variables from the model, or OPTN oversight and education for standard use/criteria of subjective variables that do have impact on the predictive power.
  - The standardization, education, communication and audit of model variable use may improve the predictive power of the model and will allay concerns that programs may achieve advantage from unintentional or intentional patterns of data submission or data omission.

Recent SRTR Changes

- **Kidney Models**
  - Changing functional form of certain variables (e.g. categorical to continuous values or splines)
  - Adding or deleting variables as well as interaction terms
- **Thoracic Models**
  - Similar changes already made after working with the OPTN Thoracic Committee
  - Additional refinements may be made in upcoming reports as the Committee continues to review models regularly
- **Liver Models**
  - January of 2009 changes were made to the Liver adult patient survival models for deceased donor transplants, including the introduction of splines and new interaction terms, as a result of work with the OPTN Liver Committee.
  - In July 2009, similar changes were made to all the graft survival models as well as the remaining patient survival models

4. Missing data

- **Missing data has been demonstrated to be a statistically significant factor for some variables**
  - **SRTR has reviewed all programs and demonstrated that patterns of missingness is rare. In addition, the data element consistently missing from one program is different than the data element missing from another program.**
  - **However, the statistical significance of this missingness in some variables needs to be studied to determine whether certain populations (e.g. sicker patients) have more significant missing data, or if there are active ("gaming") or passive (unintentional) lack of reporting**

4. Missing data

STAC Recommendations regarding missing data

- All programs must be given the opportunity to review their missing data and correct this deficit.
- Policies be developed for program performance on missing data.
- The ability to answer the question with non specific response should be eliminated (i.e. “unknown”) or reviewed.
- OPTN and SRTR should embark on an educational program to provide clear instructions on completing forms for accurate and uniform clinical responses.
- OPTN should develop a process to audit missingness and accuracy of data elements.

4. Missing data

- New data elements
  - There needs to be a process to review, add or remove data elements, based on pilot studies that demonstrate a contribution to the model.
  - Recommend that a work group including HRSA, OPTN and SRTR be formed to proactively manage this process to improve the model and to encourage research and insight into our knowledge of critical factors contributing to advancement in transplantation.
  - This data management process needs to be done on a continuous or at a minimum cyclical time.

5. Innovation

STAC recommendations regarding limitations on innovation:

- **To support innovations in transplantation science, OPTN should develop a process to prospectively review requests to exempt (or adjust for) clearly pre-defined high-risk transplant candidate populations from analysis of aggregate center data that is used for QA or PI purposes.**
- **The sub-committee believes that this should be a rare and highly selective occurrence and not used for routine clinical research.**

6. Public Concerns

STAC Recommendations regarding public concerns:

- **Address public concerns raised about the methodology with open discussion, dialogue and education amongst CMS, HRSA, OPTN, the transplant programs, and the public.**
- **This educational program should include:**
  - **information regarding the standardization of responses to data submission**
  - **clearly defined responsibilities of the Transplant Programs**
  - **clarification of the requirements for Quality Assurance as well as participation in a strong continuous Performance Improvement program specific plan.**

Summary and conclusions (1)

- The methodology currently used by the SRTR is sound, but will always need continuous review and adjustment based upon newly obtained evidence.
- There needs to be a clear distinction between performance improvement and quality assurance, and understanding by all parties involved
- The “flagging” for QA should be different than the “flagging” for PI
- The limitation of the predictive power must be acknowledged if the information is public and used for oversight or regulatory purposes

Summary and conclusions (2)

- The statistical significance of missingness in some variables needs to be studied, and policies should be developed for program education and performance review of missing data in order to minimize missingness
- Innovation in transplant science should not be deterred by concern for PSR
- There should be education and open dialogue between the OPTN, CMS, HRSA, transplant programs, and the public regarding these issues.