

The association between Cumulative Sum (CUSUM) charts provided by the Scientific Registry of Transplant Recipients and Regulatory Outcomes Review in the US

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Introduction

- In July 2013, SRTR began providing CUSUM charts to heart, kidney, liver, and lung transplant programs. The CUSUMs are intended for use as internal quality monitoring tools, but could also potentially predict future reviews by regulatory agencies (i.e., OPTN, CMS), even though the statistical procedures and included recipients differ.
- Each month, the cohort of transplant recipients included in each CUSUM chart shifts one month, and new CUSUM charts are generated. CUSUM signal thresholds are generated by simulating 500 CUSUM charts, assuming that the program is performing precisely as expected, and identifying the CUSUM value that is higher than 95% of the simulated charts. So, we expect that if a program performs exactly as expected over the entire 3-year period covered by the CUSUM chart, its chart would only produce a signal about 5% of the time.

Methods

- We produced CUSUMs with the same data used to produce the July 2012 program-specific reports—the most current reports available when the CUSUM charts were released to programs, and when the OPTN Membership and Professional Standards Committee was considering new criteria to identify programs for review.
- We compared programs whose CUSUMs produced a signal indicating possible underperformance and those that met current and proposed (Bayesian) OPTN criteria for initiating a review. By comparing the number of programs identified for review under the current and proposed MPSC algorithms, we can determine the degree that CUSUM signals agree or disagree with review criteria.
- Figure 1 shows the proposed criteria for identifying programs for review.

Results

- Agreement between CUSUM signals and identification by OPTN criteria are shown in the table for adult heart, kidney, liver, and lung programs. Of 61 programs whose CUSUM charts produced a signal, 35 (57%) were identified for review by current OPTN criteria and 41 (67%) would have been identified by the proposed OPTN criteria. Conversely, 95% of 477 programs whose CUSUM charts did not produce a signal were not identified by the current or proposed OPTN criteria.
- It is not surprising that the CUSUM signals do not precisely align with either MPSC review algorithm. The MPSC review algorithms use a slightly different cohort of transplant recipients, and are based on average program performance. CUSUM charts are designed to signal if there is a notable streak of poor outcomes even if outcomes at other times are above average.
- Results vary slightly by program type, driven largely by the mix of program volumes within the organ type.

Program Type	Total Programs	Programs with a CUSUM Signal	% with a CUSUM signal	% Identified by Current OPTN Criteria	% Identified by Proposed OPTN Criteria
Heart	117	9	8%	78%	78%
Kidney	236	26	11%	58%	65%
Liver	120	15	13%	40%	53%
Lung	65	11	17%	64%	82%
Total	538	61	11%	57%	67%

Program Type	Total Programs	Programs without a CUSUM Signal	% without a CUSUM signal	% Identified by Current OPTN Criteria	% Identified by Proposed OPTN Criteria
Heart	117	108	92%	6%	3%
Kidney	236	210	89%	3%	6%
Liver	120	105	88%	7%	8%
Lung	65	54	83%	11%	4%
Total	538	477	89%	5%	5%

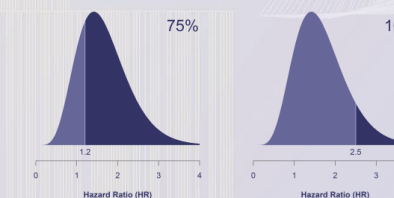


Figure 1: Graphical representation of the proposed Bayesian review criteria.

Conclusions

- CUSUM charts are not designed to predict identification for regulatory outcomes review; however, programs whose CUSUM charts produced a signal were identified for review much more often than programs whose CUSUM charts did not produce a signal. This result generally held for both the current and proposed OPTN criteria and for all organ types.