American Journal of Transplantation 2014; 14: 515–523
Wiley Periodicals Inc.

doi: 10.1111/ajt.12628

Special Article

New Quality Monitoring Tools Provided by the Scientific Registry of Transplant Recipients: CUSUM

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The Scientific Registry of Transplant Recipients (SRTR) has been providing data on transplant program performance through semi-annual release of program-specific reports (PSRs). A consensus conference held in February 2012 recommended that SRTR also supply transplant programs with tools such as the cumulative sum (CUSUM) technique to facilitate quality assessment and performance improvement. SRTR developed the process, methodologies, programming code and web capabilities necessary to bring the CUSUM charts to the community, and began releasing them to all liver, kidney, heart and lung programs in July 2013. Observed-minus-expected CUSUM charts provide a general picture of a program's performance (all-cause graft failure and mortality within the first-year posttransplant) over a 3-year period; one-sided charts can determine when performance appears to be sufficiently worrisome to warrant action by the program. CUSUM charts are intended for internal quality improvement by allowing programs to better track performance in near-real time and day to day, and will not be used to indicate whether a program will be flagged for review. The CUSUM technique is better suited for real-time quality monitoring than the current PSRs in allowing monthly outcomes monitoring and presenting data recorded as recently as 2 months before the release of the CUSUM charts.

Keywords: Graft survival, outcomes monitoring, patient survival, quality improvement

Abbreviations: ARL, average run length; CMS, Centers for Medicare & Medicaid Services; CUSUM, cumulative sum; DCD, donation after circulatory death; HRSA, Health Resources and Services Administration; MPSC, Membership and Professional Standards Committee; O–E, observed-minus-expected; OPTN, Organ Procurement and Transplantation Network; PSR, program-specific report; SPC, statistical process control; SRTR, Scientific Registry of Transplant Recipients; STAC, SRTR Technical Advisory Committee

Received 22 August 2013, revised 18 November 2013 and accepted for publication 16 December 2013

Introduction

Established by the National Organ Transplant Act, the Scientific Registry of Transplant Recipients (SRTR) exists to support the ongoing evaluation of the scientific and clinical status of solid organ transplantation in the United States (1,2). For over a decade, SRTR has been providing data on transplant program performance primarily through the semi-annual release of the program-specific reports (PSRs), which are made available to the public at www.srtr.org. The PSRs contain information on candidates awaiting transplant, transplant recipients and donors. They include outcomes statistics used by the Membership and Professional Standards Committee (MPSC) of the Organ Procurement and Transplantation Network (OPTN) to monitor program performance. In an effort to improve both the methodology and the content of the PSRs, the Health Resources and Services Administration (HRSA) of the US Department of Health and Human Services convened a consensus conference in February 2012 to gather feedback and compile a list of recommendations. This article focuses on SRTR's response to recommendation I.4:

> I.4. Provide transplant centers, the MPSC, and the Centers for Medicare & Medicaid Services (CMS) with tools such as the cumulative sum (CUSUM) technique and tools to allow subgroup analysis to facilitate quality assessment and performance improvement (3, p. 1991).

CUSUM charts are derived from a statistical process control (SPC) methodology (4). SPC uses statistics to determine when variation in a process appears to be caused by something out of the ordinary. Originally developed by Shewhart in the 1920s, SPC methodologies gained favor during and following World War II with increased demand for quality manufacturing. SPC methodologies can be applied to factory production lines to monitor when systematic variation in the process appears to have

occurred, resulting in a flawed product. The system will produce a signal notifying the managers to halt production to investigate the production line for any systematic problems (5). In recognition that these methodologies can be extended to other fields for the purpose of quality monitoring, SPC methods were extended to health care (6–8) and to transplantation (9–14). In 2010, SRTR piloted CUSUMs for liver programs to gather feedback, but did not implement routine production of CUSUM charts.

The CUSUM technique is a version of SPC that accumulates data over time as a process unfolds. In the field of transplantation, we may be interested in comparing the number of graft failures or patient deaths that occur over time with the number that would be expected if the program experienced these events at a rate consistent with the national experience for similar transplant recipients and donors. The CUSUM will signal if the accumulated data reach a predetermined threshold designed to indicate that a process review is warranted to determine whether a particular cause appears to be yielding substandard outcomes.

The CUSUM technique is better suited to support continuous quality improvement than the current PSRs for several reasons. First, the outcomes statistics presented in the PSRs provide average program performance over a 2.5-year period, whereas the CUSUMs can monitor for significant changes in outcomes that occur during a specified period of time that may be masked when average performance over a longer period of time is considered. In addition, the cohort used in the 2.5-year evaluation period is lagged behind the reporting date by at least 1 year to allow the cohort to accrue at least 6 months of follow-up time. The utility of the PSRs for monitoring real-time (or near-real time) performance is therefore limited. In contrast, the CUSUMs provide as near-real time data as possible, recognizing lags in program reporting and data processing.

The recommendation that SRTR supply CUSUM charts to transplant programs was discussed with SRTR Technical Advisory Committee (STAC). In March 2012, the STAC concurred with Consensus Conference recommendation I.4 and encouraged SRTR to explore ways to supply CUSUM charts to transplant programs on a regular basis. SRTR staff worked closely with leadership from HRSA's Division of Transplantation and members of the STAC during 2012 and early 2013 to develop the process, methodologies, programming code and web capabilities necessary to bring the CUSUM charts to the community. SRTR began releasing CUSUMs to all liver, kidney, heart and lung programs in July 2013.

A Description of the CUSUM Charts Produced by SRTR

SRTR is using a risk-adjusted CUSUM in continuous time based on the Cox proportional hazards model as described by Biswas and Kalbfleisch (11). A detailed statistical description is beyond the scope of this article; however, a few key concepts will aid users in understanding and interpreting the charts.

Data used to produce the CUSUMs

SRTR receives a full copy of the OPTN database monthly. OPTN data include supplemental death information provided through sources other than the transplant programs to identify additional deaths and dates of resumption of maintenance dialysis following a kidney transplant.

Outcomes monitored in the CUSUMs

Paralleling the outcomes currently monitored by OPTN and CMS, the CUSUMs monitor the following outcomes:

- All-cause graft failure within the first year posttransplant (or ''first-year graft survival''): The date of all-cause graft failure is the earliest of the date of retransplant of the same organ type or death. For kidney and lung recipients, the date of reported graft failure is also considered. For kidney recipients, the date maintenance dialysis resumed, as identified by CMS, is also considered.
- All-cause mortality within the first year posttransplant (or ''first-year patient survival''): the date of all-cause mortality is the date of death, regardless of transplant function.

Note that transplant recipients are monitored only during the first year posttransplant. Any outcomes that may occur beyond day 365 posttransplant do not affect the CUSUM chart.

Time period covered by the CUSUMs

Each CUSUM chart shows program performance over a 3-year period, which ends 2 months before the date the chart is released. For example, charts released in November 2013 include data through September 30, 2013, and cover the 3-year period from October 1, 2010 through September 30, 2013. The lag is necessary to allow for lag in data transfer and processing between OPTN and SRTR, and it allows some time for the programs to identify and enter outcomes into UNet^{sm}. Each CUSUM chart indicates a date 6 months before the release date, after which the chart may be less reliable due to lags in program reporting. If programs provide timely data to OPTN during this period, the charts will reflect the information and will be more useful to the programs.

Recipients included in the CUSUMs

In general, any transplant recipient with any time at risk during the 3-year interval is included. For the graft survival charts, at risk means the recipient was alive with a functioning graft on at least 1 day during the first year posttransplant; primary graft failures are included and

considered at risk for graft failure on the day of transplant. For the patient survival charts, at risk means the recipient was alive on at least 1 day during the first year posttransplant; primary failures are included and considered at risk for death on the day of transplant. Recipients contribute to the charts only on days when they were at risk. Recipients of retransplants are excluded from the patient survival CUSUM charts but are included in the graft survival charts, following current PSR conventions.

Risk adjustment used in the CUSUM charts

The CUSUM charts track observed outcomes versus expected outcomes. Expected outcomes are determined from a set of risk-adjustment models maintained by SRTR. These are the same models used to determine observed versus expected outcomes presented in the standard PSRs and can be found on the SRTR website at www.srtr.org. The risk-adjustment models take into account various donor and recipient characteristics to adjust for the case mix of the donors and recipients who undergo transplant at a particular program.

Subgroups provided

Each CUSUM report contains separate charts for adult and pediatric patient and graft survival. In addition, kidney and liver programs include separate charts for recipients of organs from deceased and living donors.

Interpreting the CUSUM Charts

When program managers access their CUSUM charts on the secure SRTR website, they find three components for each outcome (graft survival and patient survival):

1. Observed-minus-expected CUSUM charts (sometimes referred to as two-sided CUSUM charts or O–E CUSUM charts).
2. One-sided CUSUM charts.
3. Data tables containing patient-level information for patients included in the charts. These can be used to investigate the specific patients and data that contributed to the two accompanying CUSUM charts.

The observed-minus-expected CUSUM

The observed-minus-expected (O–E) CUSUM chart is useful for providing a general picture of whether a program's performance appears to be stable over the 3-year period. The O–E CUSUM chart plots the difference between the number of cumulative events that were observed on a given day and the number of cumulative events that were expected to be observed on a given day. On each day the program experiences a graft failure or death, the CUSUM line will jump upward. On each day no events occur, the CUSUM line will trend downward, as expected events continue to accumulate. A program experiencing graft failures or patient deaths at a rate higher than expected will see its O–E CUSUM line trend upward. Conversely, a program experiencing events at a rate lower than expected will see its O–E CUSUM line trend downward. A program whose performance is consistent with expectation will see its line remain relatively stable over time. Some fluctuation in the CUSUM line is expected simply due to random variation. While the O–E CUSUM chart is useful for providing a general picture of a program's performance during the 3-year period, it does not indicate when a program should be concerned and possibly take action. What indicates that the trends observed in the chart may be due to something more than random variation? The one-sided CUSUM chart is useful for making that determination.

The one-sided CUSUM chart

The one-sided CUSUM chart can be used to determine when performance appears to be sufficiently worrisome to warrant action by the program. It monitors the same patients and outcomes included in the accompanying O–E CUSUM chart and performs a statistical comparison of (1) the likelihood of observing the program's outcomes if the program truly performed as expected, compared with (2) the likelihood of observing the outcomes if the program truly had twice the expected event rate. It attempts to answer the question, ''Do the data fit better with the program having average event rates, or with the program's event rates being twice what we would expect?'' A statistical measure of the difference between the likelihood of those two hypotheses is plotted on the one-sided CUSUM chart. The absolute value and interpretation of the CUSUM value and accompanying y-axis are less important to interpreting the one-sided CUSUM. Rather, one should use the chart to identify when the data are approaching a predetermined threshold of interest. The one-sided CUSUM will increase when the hypothesis that the program has elevated event rates accumulates evidence. The one-sided CUSUM cannot drop below the starting point at the left-most end of the time period, and the line will trend upward when events occur. This does not allow programs to build up a ''credit'' during periods of good outcomes. A credit would create a situation in which a longer string of bad outcomes would be necessary to reach a predetermined threshold.

The threshold line on the one-sided CUSUM chart

Each one-sided CUSUM chart contains a threshold line across the top of the plot area. The threshold line is designed to ''signal'' when sufficient evidence has accumulated that the program's event rate is higher than expected. When the signal occurs, the chart resets to the baseline level and monitoring resumes anew.

Various methods can determine where the threshold line on the one-sided CUSUM charts should be placed (11,12,14). A common methodology is based on the

average run length (ARL). Even if a program is performing as expected, given a long enough monitoring time all charts will eventually falsely signal. The average length of time a chart runs until this false signal occurs is called the ARL. The ARL methodology can be used to determine where to draw the threshold line such that the chart will falsely signal only once in every predetermined amount of time, for example, only once in 10, 20 or 30 years of monitoring. The methodology that SRTR employs to determine the placement of the threshold line is not based on the ARL methodology. Consider that CUSUM methodologies were originally developed to monitor what is thought to be a steady-state process, such as a factory's production line producing a specific part. CUSUM charts can effectively be used to monitor that steady-state process to determine whether any change in the production process has occurred. Importantly, however, a transplant program is not a steady-state process. For example, a program may alter its transplant rate (transplants performed per year) or the case mix of the transplants performed. An ARL-based threshold designed for a program that performed 10 low-risk transplants per year would not necessarily work well if the program began performing 25 high-risk transplants per year. Therefore, SRTR decided to produce CUSUM charts that monitor a rolling 3-year period advanced monthly, not charts that start on a certain day and monitor until a signal occurs. This will allow programs to consider current performance in light of historical performance over the past 3 years.

The specific location of the threshold is designed for each program individually based on the expected event rates for patients included in each chart. Specifically, we simulate 500 CUSUM charts for each program assuming the program is performing as expected based on its daily expected event rate. For each of those 500 CUSUM charts, we determine the highest point reached, yielding 500 maximum values. The threshold is chosen to be the 95th percentile of the 500 maximum values. This yields the location of the ''5% Threshold'' on the one-sided CUSUM chart. Of the 500 simulated charts for each program, only 5% reached a point higher than the 5% threshold despite performing as expected in the simulation. Therefore, there is about a 5% chance that your chart would signal if your program was truly performing as expected during the period covered by the chart. This does not mean that only 5% of signals would be false. The percentage of signals that are false is a function of how likely the charts are to signal in error (approximately 5%) and how many underperforming programs actually exist, the latter being impossible to know with certainty. Only after careful review can a program determine if the signal appears to be true or false.

Example 1

Figure 1 shows an example of the O–E CUSUM chart (A) with its accompanying one-sided CUSUM chart (B). The O–E CUSUM chart shows a period of time when the program was experiencing events at a rate lower than predicted by the risk-adjustment models, and the chart was trending downward. This was followed by a period of time when the program was experiencing events at a rate higher than predicted by the models. Perhaps the program changed its processes, for example, its selection criteria or personnel, resulting in the observed trends. Or perhaps the trends were due to random variation. That is when the one-sided CUSUM chart becomes informative. Panel B shows the period of elevated event rates, but the chart does not reach the 5% threshold line. Therefore, we are less certain that a real problem exists that would explain the period of elevated event rates. The program may wish to investigate this time period, but knowledge that the elevated rates may be due to random variation should help inform the investigation and the program's reaction. Notice also that the one-sided CUSUM chart stays near the baseline level during the period of better than expected performance. This chart nicely demonstrates how the one-sided CUSUM chart does not allow a credit to build during times of good performance. This allows the subsequent period of poor performance to be detected sooner.

Example 2

Figure 2 shows an example of a program that was experiencing elevated event rates throughout most of the 3-year period covered by the chart. The O–E CUSUM (A) is rising steadily. Consulting the one-sided CUSUM (B), the program finds that the chart reached the 5% threshold on August 19, 2012 (note A on the right-hand side). On this date, the chart had accumulated enough evidence to conclude that the patterns observed are likely due to something other than random variation. The program should review its processes to determine whether a special cause of the pattern can be identified. The one-sided CUSUM chart resets to the baseline level following the signal to begin program monitoring again, allowing the program to reassess outcomes following the signal date and any potential changes in processes.

Will CUSUMs Indicate Whether Programs Will Be Flagged for Review by MPSC or CMS?

CUSUM charts are not used to indicate whether a program will be flagged for review by OPTN's MPSC or by CMS. CUSUM charts are meant to support program quality monitoring and improvement by allowing programs to better track performance in near-real time. In contrast, the data used by the MPSC and CMS are summaries of average performance over a 2.5-year window. Table 1 compares and contrasts the CUSUM charts with the current outcomes metrics used by the MPSC and CMS. Imagine a program that performed very well for the first half of the 2.5-year period but changed its processes and performed poorly during the second half (as in the example in Figure 1). Looking at data summarizing average performance over the

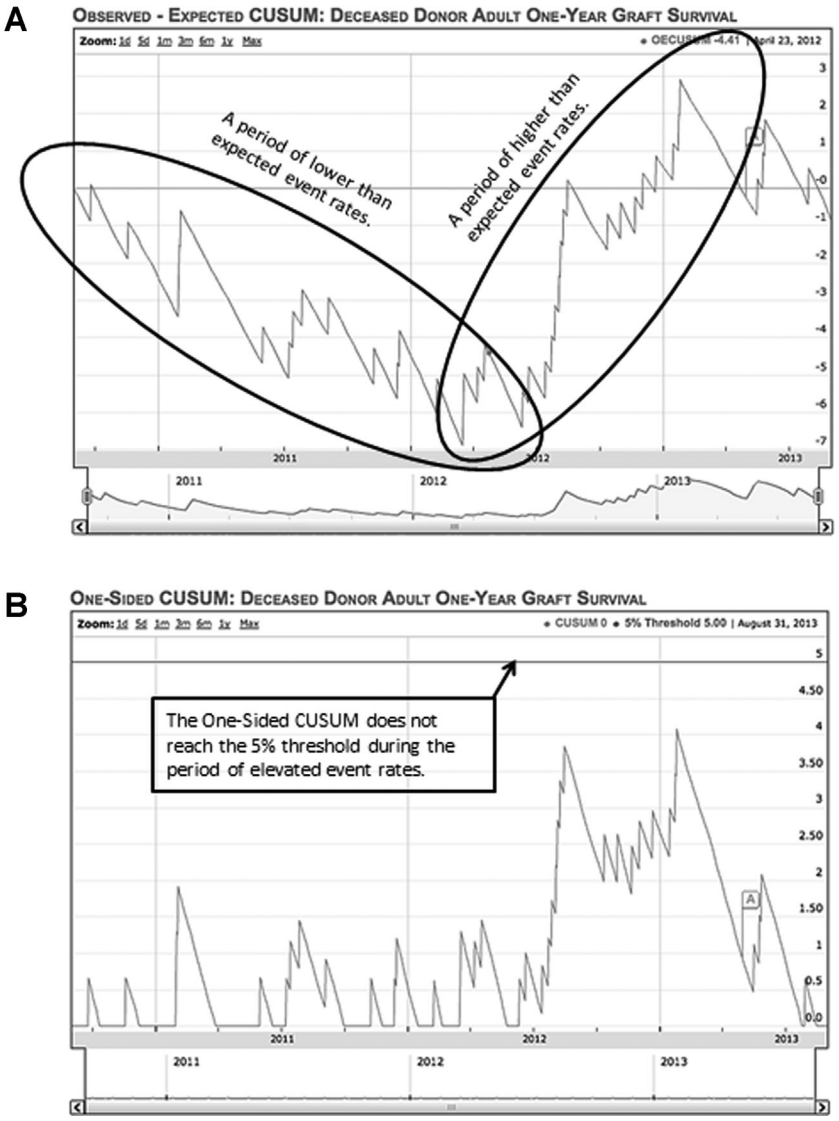

Figure 1: Example 1 of a program's observed-minus-expected (O–E) CUSUM chart (A) and the accompanying one-sided CUSUM chart (B) for deceased donor adult 1-year graft survival. This program experienced an initial period of better than expected outcomes followed by a period of worse than expected outcomes. The one-sided CUSUM chart indicates that the program's period of higher than expected event rates could be the result of random variation since the CUSUM line does not reach the 5% threshold. CUSUM, cumulative sum.

entire period, one might infer that the program's performance was as expected; however, the CUSUM chart would reveal potential problems starting during the second half of the period. Hence, the picture revealed by the CUSUM analysis will not necessarily be the same as the picture revealed in the data reviewed by the MPSC or CMS. Generally, if a program's CUSUM chart does not indicate cause for concern, the program is unlikely to be flagged by the MPSC or CMS. If the CUSUM chart indicates cause for concern (with or without reaching the 5% threshold), flagging is more likely. Figure 3 shows an example of a program with higher than expected event rates throughout most of the 3-year window (A). This program's one-sided CUSUM chart does not reach the 5% threshold during the window (B); however, its performance was sufficiently poor during the 2.5-year period reviewed by the MPSC to be flagged by current flagging criteria.

SRTR retrospectively created CUSUM charts that would have coincided with the data used for the July 2012 PSR evaluations to compare and contrast flagging with CUSUM signals. This retrospective analysis included 102 flagged programs, of which 54 (53%) also experienced a CUSUM signal. Conversely, of 93 CUSUM signals overall, 54 (58%) were also flagged by the MPSC. Of 48 programs that were flagged but did not experience a CUSUM signal, 37 (77%) were small-volume programs flagged because of at least one event. These small-volume programs do not contribute enough data to the CUSUM to achieve a signal. For the 11 mid-to-large-volume programs that were flagged but did not experience a CUSUM signal, CUSUM patterns were similar to patterns in Figure 3, where the CUSUM indicated somewhat poor performance over the span of the chart, but not enough to achieve the 5% threshold.

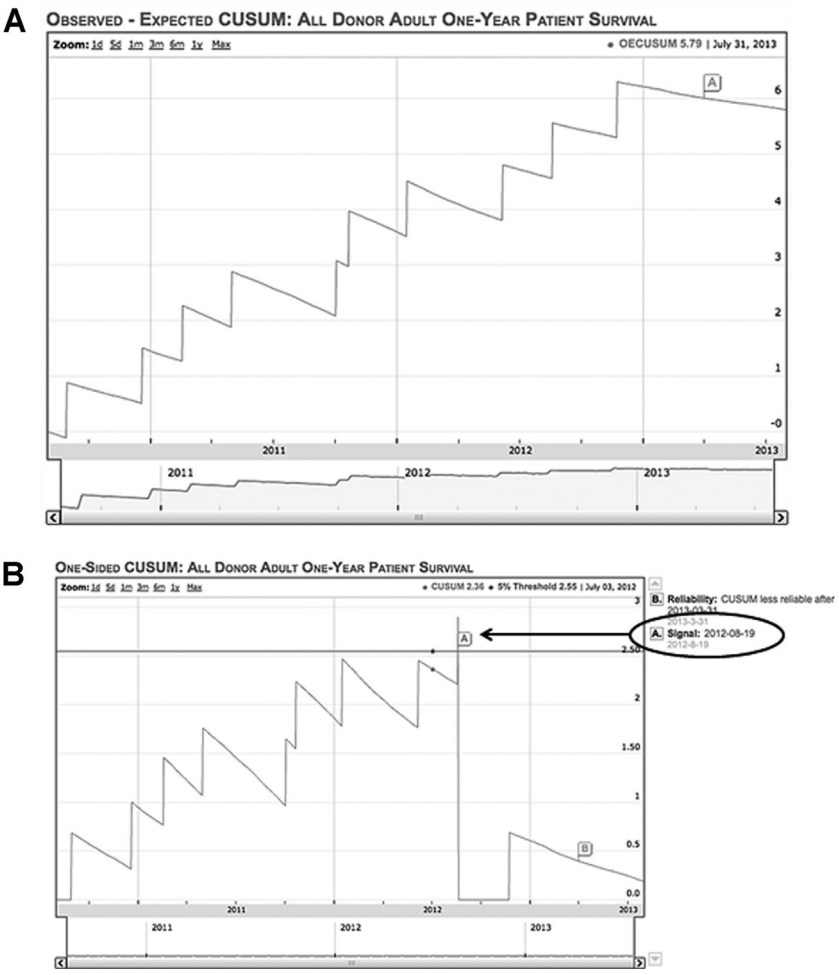

Figure 2: Example 2 of a program's observed-minus-expected (O–E) CUSUM chart (A) and the accompanying one-sided CUSUM chart (B) for all-donor adult 1-year patient survival. This program experienced events at a rate higher than expected, and the one-sided CUSUM chart signals indicate that sufficient evidence has accumulated that the observed pattern of outcomes may be the result of something other than random variation. The one-sided CUSUM chart resets to the baseline level at the time of the signal to restart the monitoring process. CUSUM, cumulative sum.

SRTR is planning to move to a Bayesian methodology of assessing program performance in the PSRs. We also compared the sample CUSUMs with the Bayesian performance thresholds currently being considered by the MPSC (document available at http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_327.pdf). The Bayesian performance assessments produced better alignment with the CUSUM signals. Of 97 programs that would have been flagged by the proposed Bayesian criteria, 61 (63%) also experienced a CUSUM signal. Conversely, of

Table 1: Comparing and contrasting CUSUM charts with outcomes assessments in the PSRs

	CUSUM	PSR outcomes measures
Purpose	Designed to allow programs to monitor their own outcomes in as near-real time as possible.	Designed to identify programs for review by MPSC because average performance over a time period appears substandard.
Time frame	Rolling 3-year window advanced monthly.	2.5-year window advanced every 6 months.
Patients included	All patients at risk during the 3-year window, that is, all patients within their first year posttransplant on any day during the window.	All patients who underwent transplant during the 2.5-year window.
Currency	Data through 2 months before the reporting date.	Most recent transplants performed at least 1 year before the reporting date.
Outcomes assessed	First-year patient and all-cause graft survival.	First-year patient and all-cause graft survival.
Signal/flag concept	Produce a signal if outcomes are substantially worse than expected for some time during the interval, even if outcomes are good at other times.	Produce a flag if average outcomes meet specific performance criteria.

CUSUM, cumulative sum; MPSC, Membership and Professional Standards Committee; PSR, program-specific report.

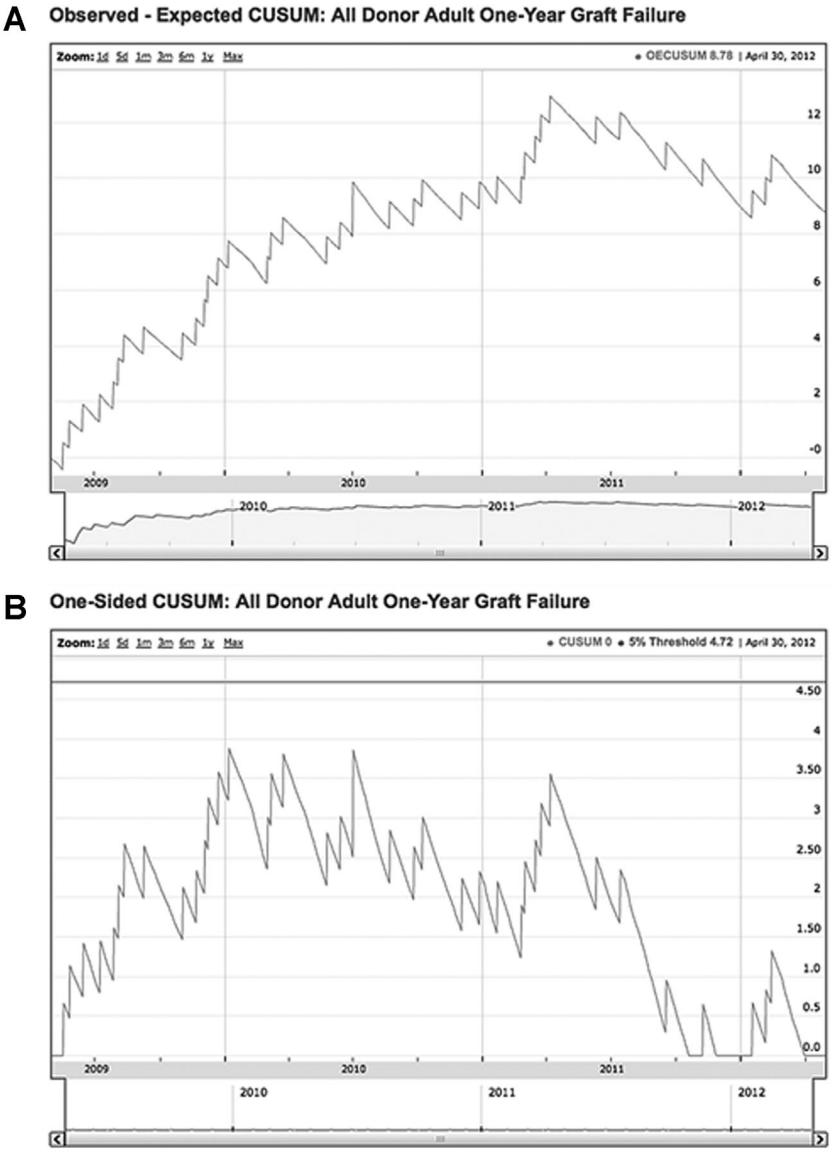

Figure 3: Example 3 of a program's observed-minus-expected CUSUM chart (A) and the accompanying one-sided CUSUM chart (B) for all-donor adult 1-year graft failure. This program was experiencing higher than expected event rates over the period of the chart, but the one-sided CUSUM did not reach the 5% threshold line. This is an example of a program that met the Membership and Professional Standards Committee flagging criteria because of a sustained level of underperformance during the 2.5-year period included in the program-specific report evaluation, but the level of underperformance was not sufficient to cause a CUSUM signal over the 3-year window covered by the CUSUM. CUSUM, cumulative sum.

93 CUSUM signals, 61 programs (66%) also met the Bayesian flagging criteria.

Discussion

At the Consensus Conference on Transplant Program Quality and Surveillance, SRTR was encouraged to explore developing tools for transplant programs to monitor outcomes on a more real-time and near-time basis. Two common complaints about the standard quality outcomes metrics presented in the PSRs are that the data are (1) old and (2) not granular enough in that the PSR outcomes summarize average performance over a 2.5-year period. CUSUM methodologies present transplant programs with the opportunity to monitor outcomes on a daily basis and can present data as recent as 2 months before the release of the charts, thereby addressing these two common complaints.

SRTR is releasing monthly updates to the CUSUM charts for programs to review. These charts are being supplied to transplant programs on their secure SRTR websites to be used for internal quality monitoring. SRTR will not release CUSUM charts to third parties. However, programs can decide whether and with whom to share their own CUSUM charts.

While the hope is that the CUSUM charts will help drive quality improvement, SRTR recognizes the potential for unintended consequences. One unintended consequence is the possibility that insurance providers may request access to the CUSUM charts. CUSUM charts are intended to enable continuous quality monitoring within programs,

not to make comparisons across programs. The charts can detect shifts in internal processes that may result in substandard performance, but caution should be used regarding any conclusion that one program is superior to another on the basis of CUSUM charts. One intended consequence is progress toward continuously monitoring outcomes and developing plans to respond in the event of a signal. Programs with such plans in place will hopefully be viewed favorably by third-party payers. SRTR encourages programs to develop capabilities in monitoring and understanding their CUSUM charts.

SRTR chose to draw the signal boundary at the 5% threshold. This is a subjective decision, but one intended to find a balance between creating too many false signals, thereby creating needless concern, and failing to identify potential problems quickly enough when they exist. If programs draw the signal boundaries themselves, the decision of where to place the boundary should reflect the program's preplanned reaction to the signal. If a program plans to perform an extensive review of all processes, it may wish to draw a more conservative (higher) threshold line that is less likely to yield a false signal. On the other hand, if a program plans a less extensive review process and would prefer earlier warning signals with the understanding that false signals are more likely, it could choose to draw a less conservative (lower) threshold line. The 5% threshold line is provided as a fairly conservative indicator. We emphasize, however, that programs should ideally discuss and plan what their response will be if the one-sided CUSUM chart reaches the threshold.

CUSUM charts can help alert programs to the possibility of a problem, but they do little to identify the nature of the problem. As a result, some programs may respond irrationally to their CUSUM charts. The risk-adjustment models take many donor and recipient characteristics into account; however, and importantly, no risk-adjustment model is perfect. Programs should become familiar with the risk-adjustment models (www.srtr.org) to better understand (1) which elements are included in the models and (2) how each element relates to expected risk for each patient. Programs may identify characteristics of their patients that are not accounted for in the risk-adjustment models and could result in the trends seen in the CUSUM charts. It may not be prudent for a program with poor outcomes for low-risk recipients but good outcomes for high-risk recipients to respond to a CUSUM signal by performing more transplants in low-risk candidates and fewer in high-risk candidates. For example, reducing the number of transplants from donation after circulatory death (DCD), donors may not be the appropriate action when the risk-adjustment models include an adjustment for DCD donation and outcomes were as expected for DCD recipients. In addition to the various CUSUM charts provided for deceased and living donors and adult and pediatric recipients, SRTR supplies all programs with an Expected Survival Worksheet, which allows programs to perform their own subgroup analyses to gain insight into which patients may be contributing to lower than expected outcomes. Programs should not overreact to a CUSUM chart without first attempting to understand this. Furthermore, reacting early to a CUSUM chart that is approaching the trigger line increases the likelihood of reacting when trends may be due to random variation; in other words, the program may react and expend resources when no problem was occurring. Planning in advance will lessen the likelihood of a possibly unwarranted reaction.

Finally, SRTR supplies subgroup analyses by donor type for kidney and liver programs. The more subgroups are provided, the higher the likelihood of false signals. Hopefully, the subgroup CUSUM charts are helpful as programs begin to identify which patient groups may be contributing to any observed problems, or if results appear consistent within subgroups. However, we urge caution in interpreting signals within subgroups when the overall chart does not indicate a signal.

Notwithstanding the potential for unintended consequences, we hope the CUSUM charts will enhance each program's ability to monitor its outcomes, to improve quality improvement processes and ultimately to enhance patient outcomes. The donor pool remains inadequate to meet the demand of recipients in need of a life-saving or life-enhancing transplant. The transplant system in the United States owes it to our patients and donor families to be the best possible stewards of the gift of life that we collectively can be. Any suggestions to improve the information SRTR supplies to the transplant community may be submitted by e-mail to srtr@srtr.org.

Acknowledgments

This work was conducted under the auspices of the Minneapolis Medical Research Foundation, contractor for SRTR, as a deliverable under contract HHSH250201000018C (US Department of Health and Human Services, HRSA, Health-Care Systems Bureau, Division of Transplantation). As a US Government-sponsored work, there are no restrictions on its use. The views expressed herein are those of the authors and not necessarily those of the US Government. The authors thank SRTR colleagues Delaney Berrini, BS, for manuscript preparation, and Nan Booth, MSW, MPH, ELS, for manuscript editing. The authors also thank the members of the STAC for their advice in the development of the CUSUM charts and the anonymous editors and reviewers of earlier drafts of the manuscript for their many helpful comments.

Disclosure

The authors of this manuscript have no conflicts of interest to disclose as described by the *American Journal of Transplantation*.

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