Special Article

Potential Implications of Recent and Proposed Changes in the Regulatory Oversight of Solid Organ Transplantation in the United States

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Every 6 months, the Scientific Registry of Transplant Recipients (SRTR) publishes evaluations of every solid organ transplant program in the United States, including evaluations of 1-year patient and graft survival. The Centers for Medicare & Medicaid Services (CMS) and the Organ Procurement and Transplantation Network (OPTN) Membership and Professional Standards Committee (MPSC) use SRTR's 1-year evaluations for regulatory review of transplant programs. Concern has been growing that the regulatory scrutiny of transplant programs with lower-than-expected outcomes is harmful, causing programs to undertake fewer high-risk transplants and leading to unnecessary organ discards. As a result, CMS raised its threshold for a "Condition-Level Deficiency" designation of observed relative to expected 1-year graft or patient survival from 1.50 to 1.85. Exceeding this threshold in the current SRTR outcomes report and in one of the four previous reports leads to scrutiny that may result in loss of Medicare funding. For its part, OPTN is reviewing a proposal from the MPSC to also change its performance criteria thresholds for program review, to review programs with "substantive clinical differences." We review the details and implications of these changes in transplant program oversight.

Abbreviations: CMS, Centers for Medicare & Medicaid Services; HR, hazard ratio; KDPI, kidney donor profile index; MPSC, Membership and Professional Standards Committee; O/E, observed relative to expected; OPTN, Organ Procurement and Transplantation Network; PSR, program-specific report; SRTR, Scientific Registry of Transplant Recipients

Introduction

Advances in communication and social media technology have helped fuel a revolution in providing information on healthcare services to the general public. Ratings of healthcare providers are now commonplace (1–6). For solid organ transplantation, the Final Rule explicitly mandates that the Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR) "Make available to the public timely and accurate program-specific information on the performance of transplant programs" (7). Increasing public scrutiny of transplant program outcomes has raised concerns about unintended harms to transplant programs and to patients. Some programs may believe that performing higher-risk, but clinically justified, transplants increases the likelihood of a poor public evaluation. Resulting risk-averse behavior could lead to more discarded organs and fewer patients benefiting from transplant. Partly in response to these concerns, the Centers for Medicare & Medicaid Services (CMS) has altered its "Condition-Level" review criteria, and OPTN is reviewing proposals to modify its review criteria.

Regulatory Oversight of Transplantation in the United States

The Scientific Registry of Transplant Recipients

SRTR releases program-specific reports (PSRs) on all transplant programs in the United States every June and December. These reports include risk-adjusted assessments of 1-year graft and patient survival based on 2.5-year transplant cohorts, and programs performing better or worse than expected are identified (www.srtr.org). SRTR began using Bayesian statistical methodology to assess program performance in December 2014 (Table 1) (8). The publicly available reports present the program's hazard ratio (HR, a measure of observed relative to expected [O/E] performance) along with a 95% credible interval for the HR; however, the publicly available reports do not currently indicate whether the program meets OPTN or CMS regulatory review thresholds. Programs are instead given a separate report indicating whether they meet these review criteria.

Table 1: Changes in methods used for screening transplant programs based on first-year transplant outcomes

SRTR Public Reports	
Before December 2014	After December 2014
If O/E > 1.0 and 2-sided p-value < 0.05, then "lower than expected" survival indicated.	If the lower bound of the 95% credible interval of the [Bayesian] hazard ratio is >1.0, then "lower than expected" survival indicated.
If O/E < 1.0 and 2-sided p-value < 0.05, then "higher than expected" survival indicated.	If the upper bound of the 95% credible interval of the [Bayesian] hazard ratio is <1.0, then "higher than expected" survival indicated.

MPSC	
Current (after December 2014)	Proposed
If p[HR > 1.2] > 75%,[1] then 100% reviewed.	If p[HR > 1.75] > 60%, then 100% reviewed.
If p[HR > 2.5] > 10%, then 100% reviewed.	If p[HR > 1.25] > 60%, then 50% randomly reviewed.
	If HR > 1.00, then 10% randomly reviewed.

CMS	
Before May 13, 2016	Beginning May 13, 2016
If O/E > 1.5 and O − E > 3 and 1-sided p-value < 0.05, then "Standard-Level Deficiency."	If O/E > 1.5 and O − E > 3 and 1-sided p-value < 0.05, then "Standard-Level Deficiency."
If O/E > 1.5 and O − E > 3 and 1-sided p-value < 0.05 on at least 2 of 5 consecutive PSRs, then "Condition-Level Deficiency."	If O/E > 1.85 and O − E > 3 and 1-sided p-value < 0.05 on at least 2 of 5 consecutive PSRs, then "Condition-Level Deficiency."

CMS, Centers for Medicare & Medicaid Services; HR, hazard ratio; MPSC, Membership and Professional Standards Committee; O/E, observed relative to expected events; PSRs, program-specific reports; SRTR, Scientific Registry of Transplant Recipients.
[1]Probability that the HR exceeds the value indicated, eg p[HR > 1.2] > 75%, indicates a more than 75% probability that the HR exceeds 1.20.

The Organ Procurement and Transplantation Network

SRTR periodically submits to the Membership and Professional Standards Committee (MPSC) a list of transplant programs whose 1-year graft and/or patient survival meets MPSC screening criteria (Table 1). The MPSC then reviews the programs and determines what response, if any, is necessary. On December 1, 2016, the OPTN board of directors formed a work group and asked the MPSC to provide the board with a proposal for an improved system to identify "substantive clinical differences in patient and graft outcomes" (9). The work group met several times over 4 months and ultimately proposed changing the MPSC criteria used to identify programs that may be underperforming.

The newly proposed MPSC system for identifying underperforming programs includes four tiers (Figure 1):

(1) Programs for which the probability is greater than 60% that their adjusted HR is greater than 1.75 will all be reviewed by the MPSC.
(2) Fifty percent of the remaining programs whose probability is greater than 60% that their adjusted HR is greater than 1.25 will be subjected to a random review.
(3) Ten percent of the remaining programs with an adjusted HR greater than 1.00 will be randomly selected for review.

(4) Programs for which the adjusted HR is 1.00 or less will not be reviewed.

These criteria will be applied to graft survival and patient survival evaluations, and a program's review status will be determined by whichever evaluation is worse.

The Centers for Medicare & Medicaid Services

Since mid-2007, CMS Conditions of Participation require that each solid organ transplant program maintain patient and graft survival rates within CMS tolerance limits (Table 1). CMS uses SRTR data, although not the recently implemented SRTR Bayesian methodology, to determine whether program outcomes are within CMS tolerance limits. Starting with the July 2007 SRTR cohort, CMS began identifying programs with "Standard-Level Deficiency" if the O/E 1-year graft or patient survival in the most recent 2.5-year review cycle exceeded 1.50. If this occurred in the most recent cohort and in one of the four previous cohorts, CMS considered it a "Condition-Level Deficiency." CMS recently reported that in the July 2015 cohort, 3.4% of all programs were given a Standard-Level Deficiency and 1.7% a Condition-Level Deficiency (CMS presentation given by Thomas Hamilton, March 10, 2016). Between July 2007 and July 2015, 70% of programs with a Standard-Level Deficiency developed a Condition-Level Deficiency. Programs with a Condition-Level Deficiency have 210 days to appeal to CMS that their outcomes are poor owing to "mitigating
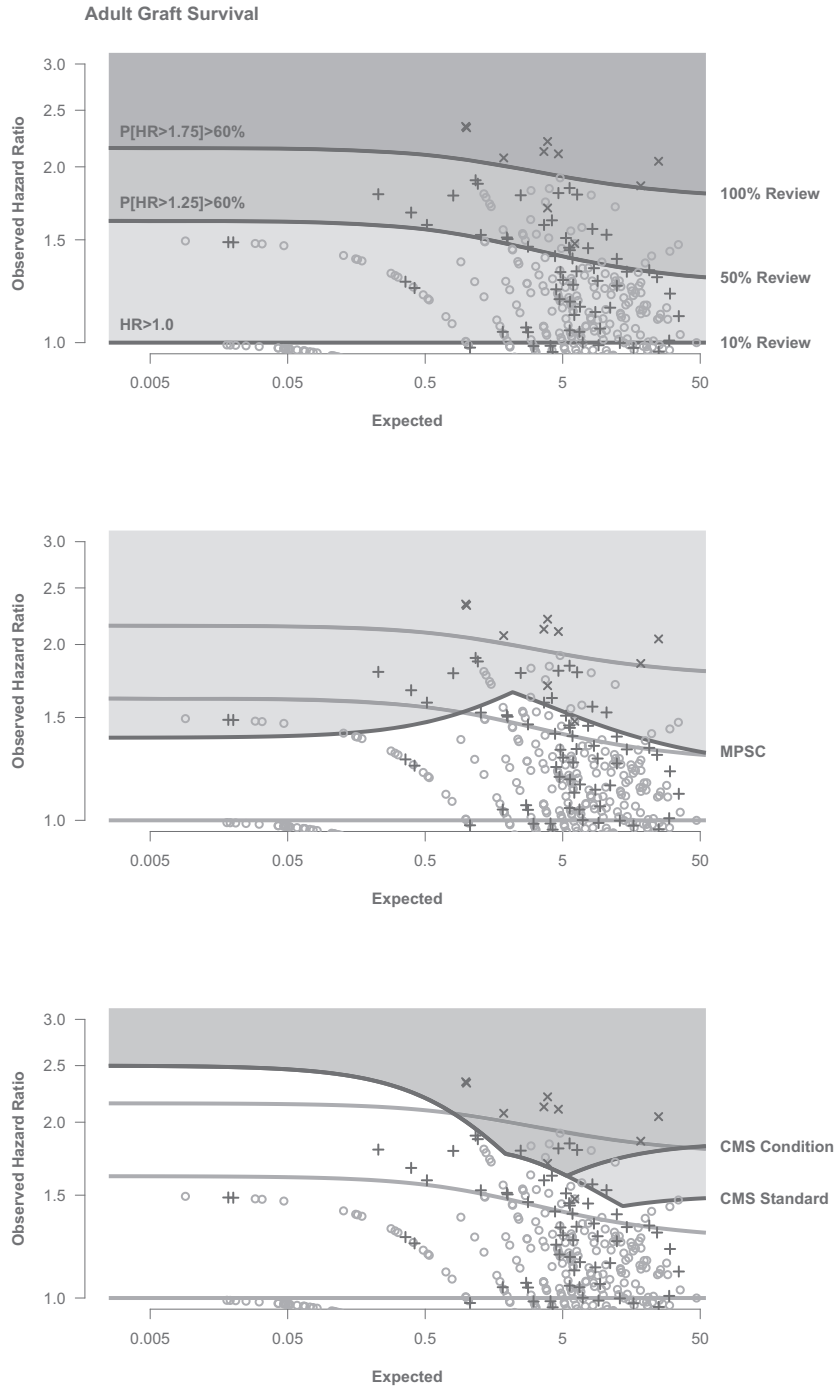
Figure 1: Programs meeting threshold criteria for 1-year adult graft survival in the 2.5-year SRTR evaluation cohort for the PSRs released in December 2015. The upper panel shows the number of programs identified for review under the newly proposed MPSC criteria, the middle panel compares this with the former MPSC criteria and the lower panel compares it with the former and current CMS criteria. Circles indicate programs not identified by MPSC for review; ×'s indicate programs identified because the probability that the HR exceeded 1.75 was over 60% (100% reviewed); +'s indicate programs identified for random review because the probability that the HR exceeded 1.25 exceeded 60% or the HR exceeded 1.00, of which 50% or 10% were randomly selected for review, respectively. CMS, Centers for Medicare & Medicaid Services; HR, hazard ratio; MPSC, Membership and Professional Standards Committee; p, probability; PSRs, program-specific reports; SRTR, Scientific Registry of Transplant Recipients.

factors" or they must undertake measures to improve their outcomes or terminate the program. Between July 2007 and July 2015, 145 programs with a Condition-Level Deficiency completed this 210-day adjustment period. Of these programs, 28 (19.3%) improved their outcomes and were in compliance, 55 (37.9%) had mitigating factors approved by CMS, 45 (31.0%) were required by CMS to establish a Systems Improvement Agreement, and 17 (11.7%) were terminated.

On May 13, 2016, CMS released revised Survey and Certification interpretive guidelines (10). "Medicare approval will generally not be at risk solely due to noncompliance with the outcomes standards … so long as a transplant program's O/E ratio is within 185% of the risk-adjusted expected number" (Table 1). In making this change, CMS noted improved patient and graft survival rates since 2007 and that "the national improvement has made the CMS outcomes standard increasingly stringent and made it more difficult for individual transplant programs to maintain compliance." CMS expressed concern "that transplant programs may be avoiding use of certain available organs that they believe may adversely affect the program's outcome statistics."

Private insurance providers

Insurance providers may use SRTR reports to help determine which transplant programs to use for their patients. They may have their own methods for using program-specific data along with other information to make this determination, and they may be reluctant to designate a program as a "center of excellence" if it is underperforming in SRTR reports.

A Comparison of Different Methods Used to Identify Underperforming Programs

We used data from the SRTR, which include data on all donors, waitlisted candidates, and transplant recipients in the United States, submitted by the members of the OPTN. The Health Resources and Services Administration, US Department of Health and Human Services, provides oversight of the activities of the OPTN and SRTR contractors.

We used the 2.5-year cohort of solid organ transplants from January 1, 2013, through June 30, 2015, ie the cohort used in the PSRs published in December 2015. We determined the number of programs that would be identified as underperforming comparing different criteria: used by CMS (1) before and (2) after May 13, 2016, (3) used by the MPSC currently, and (4) as proposed by the MPSC to the OPTN board of directors at the June 6–7, 2016, meeting (Table 1). Of note, programs meeting threshold criteria for determining underperformance are handled differently by CMS and the MPSC.

The newly proposed MPSC criteria would identify approximately the same number of programs as do the current criteria (Table 2) but would tailor the intensity and process of review to the probability and magnitude of underperformance (Figure 1). Only programs with extreme outlying performance are guaranteed an MPSC review. The next two tiers progressively assign decreasing probabilities of review for every program with an HR above 1.0. By expanding the number of programs subject to potential review but keeping the same number of reviews, the proposed MPSC criteria shift the focus of review away from programs with the worst observed performance to programs with better observed performance. For example, given the same number of expected events, a program with an HR of 1.70 is *not guaranteed* to be reviewed before a program with an HR of 1.05. Partly due to the shift away from identifying programs with the worst observed performance, and partly because the CMS Condition-Level boundary is outside the OPTN's proposed 100% review tier (Figure 1), CMS could designate a program with Condition-Level Deficiency before the MPSC reviews it. If a program is within the high-frequency review zone for two consecutive cycles, it has a 25% probability of not being selected

Table 2: Comparison of numbers of programs identified for possible further review[1]

| Organ transplant | CMS | | | | MPSC | | | | |
| | "Standard-Level" | | "Condition-Level" | | | Proposed criteria | | | |
	Before May 2016	After May 2016	Before May 2016	After May 2016	Current	100% Review tier	50% Review tier	10% Review tier	All tiers
Kidney	18	18	10	8	32	8 of 8	17 of 34	8 of 81	33
Heart	6	6	2	2	12	2 of 2	7 of 14	5 of 45	14
Liver	5	5	4	2	14	1 of 1	10 of 20	5 of 49	16
Lung	3	3	2	1	12	1 of 1	7 of 13	2 of 20	10
All organs	32	32	18	13	70	12 of 12	41 of 81	20 of 195	72

CMS, Centers for Medicare & Medicaid Services; MPSC, Membership and Professional Standards Committee.
[1]Numbers represent numbers of programs identified for possible review during the program-specific report evaluation cohort released in December 2015; actual numbers reviewed by MPSC or CMS may be lower because some programs were already under review or had been recently released from review.

for MPSC review, at which point CMS may cite a Condition-Level Deficiency.

Through a series of simulations (see Supplemental Methods and Tables), we examined the statistical properties of the screening algorithms (sensitivity, specificity, positive predictive value and negative predictive value) comparing (1) the former CMS criteria, (2) the new CMS criteria, (3) the current MPSC criteria and (4) the newly proposed MPSC criteria (Table 3). If underperformance is defined as an HR greater than 1.00, the sensitivity (probability that a program would be flagged if the HR is high) is highest for the current MPSC criteria (25.8%) and lowest for the current CMS criteria (13.5%). The positive predictive value (probability that the HR is high if the program is flagged) is highest for the new CMS criteria (97.2%) and lowest for the proposed MPSC criteria (88.2%). The specificity (probability that a program is not flagged if the HR is low) is highest for the new CMS criteria (99.7%) and lowest for the newly proposed MPSC criteria (97.4%). The negative predictive value (probability that the HR is low if the program is not flagged) is lowest for the new CMS criteria (57.8%) and highest for the current MPSC criteria (61.2%). The proposed MPSC criteria perform worse than the current MPSC criteria on all four properties. Although these differences are numerically small, they indicate that the newly proposed MPSC criteria constitute a uniformly less efficient screening algorithm. If the MPSC proposal is adopted, more identified programs will not be underperformers (more false positives), and fewer underperforming programs will be identified (fewer true positives), relative to the current MPSC screening algorithm.

Discussion

The goal of regulatory review is to ensure that transplant program outcomes nationwide meet current standards after adjustment for recipient and donor risk. Both the MPSC and CMS choose to review programs that appear to be underperforming at a predetermined statistical threshold. Recent controversy over whether too many programs are being reviewed has led to a change in the CMS threshold for review and proposed changes in the MPSC threshold for review. Choosing an optimal set of screening criteria requires evaluating the trade-offs involved. In this case, we need to consider the performance of the screening test itself, the effectiveness of review and the effect of the review system on program behavior. Patients can be harmed when programs become risk averse, but patients can also be harmed when underperforming programs have insufficient incentives to improve.

The proposed MPSC criteria raise several concerns. First, they will lead to review of programs with little underperformance as programs with much greater underperformance escape review. Second, the proposed criteria increase the pool of programs that could be reviewed, which may encourage more, rather than fewer, programs to be risk averse. Third, there is little evidence that the proposed changes will increase the number of transplants. In fact, it is unclear whether current regulatory scrutiny reduces the number of transplants or shifts transplants from programs with worse outcomes to programs with better outcomes. Finally, the proposed MPSC criteria directly negate the desire of CMS for the OPTN/MPSC to serve as the initial step in the quality improvement process (10).

It has been argued that a less punitive system for improving transplant program outcomes could achieve the same results with fewer adverse consequences. The US Health Resources and Services Administration currently funds the transplant Collaborative Improvement Innovation Network to define outcomes and processes that differentiate excellence in transplant programs. The

Table 3: Simulated performance of different screening algorithms (prior variance = 0.5)

Screening criteria	Underperformance[1]	Prevalence, %[2]	Sensitivity, %	Specificity, %	PPV, %	NPV, %
Current CMS	1.00	45.7	13.5	99.7	97.2	57.8
Previous CMS	1.00	45.7	19.0	99.5	96.9	59.3
Current MPSC	1.00	45.7	25.8	98.7	94.2	61.2
Proposed MPSC	1.00	45.7	23.1	97.4	88.2	60.1
Current CMS	1.25	27.8	20.3	99.0	89.2	76.4
Previous CMS	1.25	27.8	27.3	98.1	84.8	77.8
Current MPSC	1.25	27.8	36.0	96.5	79.8	79.6
Proposed MPSC	1.25	27.8	30.3	95.1	70.3	78.0
Current CMS	1.50	16.1	28.7	98.0	73.0	87.7
Previous CMS	1.50	16.1	34.6	96.0	62.2	88.4
Current MPSC	1.50	16.1	43.9	93.5	56.5	89.7
Proposed MPSC	1.50	16.1	36.5	92.7	49.1	88.4

CMS, Centers for Medicare & Medicaid Services; MPSC, Membership and Professional Standards Committee; NPV, negative predictive value; PPV, positive predictive value.
[1]The value is the minimum hazard ratio to be considered underperforming.
[2]The prevalence column is the fraction of programs considered to be underperforming.

quest to discover "best practices" that programs can emulate is laudable. However, one can argue that the success or failure of these efforts should be judged by their effects on patient and graft survival.

Risk adjustment models might be improved by collecting additional data (11–13). The influence a missing risk factor would have on a program's evaluation is determined by (1) how frequently a program performs transplants with this risk factor, (2) how large an effect the risk factor has on outcomes and (3) how correlated the risk factor is with other factors already included in the model. Risk factors important for improved risk stratification should be collected. This is critical for ensuring that transplant programs are not discouraged from performing transplants with donors or candidates with risk factors not currently collected.

Avoiding suitable but high-risk transplants to avoid regulatory scrutiny is ill-conceived and ineffective, assuming the risk is measured and adjusted for in the models. A recent analysis demonstrated that transplant programs do not come under regulatory scrutiny solely on the basis of underperformance on high-risk transplants (14). Nevertheless, the perception of many transplant programs is that risky transplants and innovations can cause program outcomes to appear worse and result in lost contracts and referrals (15). Thus, programs with worse outcomes reduce the numbers of transplants they perform and preferentially avoid accepting high-risk recipients and donors (16,17). This is not necessarily bad if these transplants are performed by other programs and overall access to transplant remains unaffected. In general, numbers of transplants in the United States have increased and outcomes have improved in the face of increased regulatory scrutiny.

It has been suggested that high-risk transplants be removed from regulatory oversight (18). This could theoretically prevent programs from avoiding these transplants. However, the challenges to this approach are formidable: (1) There is no relationship between the number of high-risk transplants performed by a program and its overall performance evaluation (14). (2) Excluding high-risk transplants would unfairly disadvantage programs that perform high-risk transplants well. (3) Removing high-risk transplants may have the unintended consequence of causing programs to fear performing even lower-risk transplants; if kidney transplants from donors with a kidney donor profile index (KDPI) of 85% or higher were excluded from evaluation, programs may begin avoiding transplanting kidneys in the KDPI 80–84% range because these are now the "riskiest" transplants being evaluated. (4) It would be difficult to establish an equitable process to determine what transplants constitute high risk. (5) Selectively removing transplants from the SRTR analyses will reduce the statistical power of these analyses and weaken their ability to identify underperforming programs.

The newly released CMS interpretive guidelines raised the bar from 1.50 to 1.85 for designating programs as Condition-Level Deficiency. One motivation for this change was that programs may be at higher risk of review owing to the overall improvement in national outcomes since the CMS Conditions of Participation initially went into effect in 2007. However, because the CMS and MPSC criteria are a function of the expected number of events, improved outcomes have made it harder rather than easier for programs to meet the CMS and MPSC screening criteria (eg in Figure 1 the HR required for review increases as the number of expected events decreases). Additionally, any system that assesses performance using an absolute threshold (eg minimum 95% survival) or an absolute difference between observed and expected survival (eg within 5% of expected survival) creates incentives to avoid risky transplants because the easiest way to ensure compliance with these absolute thresholds is to avoid high-risk transplants. Because adjusting for donor and recipient risk ensures that programs are not unfairly punished for performing high-risk transplants, screening algorithms for reviewing transplant programs should use risk-adjusted relative metrics of performance (eg the HR).

The current system functions reasonably well. It identifies programs with lower-than-expected outcomes, allows the MPSC to conduct nonpunitive audits that encourage programs to improve and allows CMS to intervene with more stringent measures when MPSC efforts fall short. However, the current system could be improved. SRTR should continue to make the case that risk adjustment works and programs need not be averse to performing suitable high-risk transplants. OPTN should collect additional variables that allow SRTR to continuously adapt and improve risk-adjusted models. Additional metrics should also be considered to broaden program evaluations. Long-term outcomes could be examined. Because programs have a responsibility to ensure patient access to transplant, appropriate pretransplant metrics should be developed. Programs should be held accountable for accepting suitable organs for candidates on their waiting lists, and SRTR is exploring methods of examining rates of organ offer acceptance. Similarly, collecting new data and finding new metrics for organ recovery efficiency may encourage hospitals, organ procurement organizations and transplant programs to increase the utilization of organs that are currently not recovered for transplant or are recovered but discarded.

In summary, the newly adopted CMS screening algorithm and the proposed MPSC screening algorithm perform worse than those previously (CMS) or currently (MPSC) in place. Additionally, there is little evidence that the new screening algorithms will reduce risk aversion, and they may fail to increase the number of transplants. Weakening oversight of programs with the hope of encouraging them to perform more transplants may

ultimately not be in the best interest of patients, nor in the best interest of donors and their families who hope for the best possible outcomes from their gift of life. Ultimately, better education efforts regarding the risk-adjustment process and improved risk adjustment through better data collection may help dispel risk aversion without weakening the quality of oversight systems in place.

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Disclosure

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Supporting Information

Additional Supporting Information may be found in the online version of this article.

Data S1: Supplemental methods.

Table S1: Simulated performance of different screening algorithms (prior variance = 0.25).

Table S2: Simulated performance of different screening algorithms (prior variance = 0.167).

Table S3: Simulated performance of different screening algorithms (prior variance = 0.125).