Factors predicting the risk of loss of decisional capacity for Medical Assistance in Dying (MAiD) in Canada: the key importance of Palliative Performance Scale. A retrospective database review.

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Abstract

Background: Bill C-14 legalized Medical Assistance in Dying (MAiD) in Canada, outlining eligibility criteria and including both a mandated 10-day wait period and capacity to consent at the time of MAID provision. This wait period can be waived for patients deemed at risk of loss of capacity. Our study examined clinical factors associated with shortened wait times and/or loss of capacity prior to provision of MAiD.

Methods: This was a retrospective database review of patients requesting a MAiD assessment between July 2016 and April 2019. Logistic regression analyses examined the association between the combined outcome of shortened 10-day wait period or unanticipated loss of decisional capacity/death and the clinical risk factors of interest (age, location of MAiD request, palliative performance scale (PPS), primary diagnosis, and palliative care involvement)**.** Receiver Operating Characteristic (ROC) curves were generated to identify the PPS score best predictive of losing capacity, shortened wait time or death.

Results: 155 patients were assessed for MAiD eligibility. Eighteen died or lost capacity during the 10-day wait period and 49 patients had their wait period shortened. Patients with a lower PPS had significantly increased odds of losing capacity/shortening of the 10-day wait period (OR 0.850, 95% CI *0.803 - 0.900,* p<0.0001). The ROC curve optimizing both sensitivity and specificity for predicting loss of capacity/shortening of wait time identified a PPS score of 30% with greater sensitivity noted at PPS 40%.

Interpretation: Patients whose PPS is 40% or below when they request MAiD are more likely to need their wait period shortened and should be vigilantly monitored to this end.

Introduction

Medical Assistance in Dying (MAiD) was decriminalized by the Supreme Court of Canada in February 2015 (1), and Canada's federal legislation on MAiD (Bill C-14) was passed June 17, 2016 (2). Since that time, close to 7000 Canadians have accessed MAiD (3). Canada is part of a growing number of international jurisdictions affording individuals the right to an assisted death, including regions in Europe, the Unites States, Latin America and Australia (4-9). In Canada, eligibility requirements for MAiD stipulate that the patient be at least 18 years of age, make a voluntary request, possess capacity to provide consent for MAiD, and have a grievous and irremediable medical condition. The latter is defined as an illness, disease or disability resulting in an advanced state of irreversible decline wherein the patient is experiencing intolerable physical or psychological suffering and whose natural death has become reasonably foreseeable. Patients deemed eligible for MAiD by two independent physicians or nurse practitioners must fulfill a ten-day reflection period before MAiD can be provided, and must retain capacity to provide final consent immediately prior to provision (2). Following provision of MAiD there is mandatory reporting by practitioners at the federal level for monitoring (10) and at the provincial level for oversight, with this process varying across provinces (11).

Prior work has highlighted the importance that patients place on receiving MAiD once they have made the decision to proceed (12,13,14). For those who are seriously ill or felt to be at risk of losing capacity to provide final consent, the 10-day wait period can be a source of marked anxiety for the patient, with providers needing to balance patient-centered care with adherence to the legislation. The wait period can be waived if both assessors feel the patient is at imminent risk of death or loss of capacity, but to date there is no evidence-based data on this population of patients. In Ontario, as of September 30, 2019, 24% of patients had a shortened wait time (15), but nevertheless there are patients who die or lose capacity prior to provision (12). The goal of this study was to identify clinical factors associated with shortened wait times or the loss of capacity to consent prior to provision of MAiD.

Methods

Study design and participants:

We retrospectively reviewed our institutional MAiD database, maintained since the enactment of MAiD legalisation, which includes all adults age 18 years or older who made a formal request for a MAiD eligibility assessment between July 2016 and April 2019 at a large academic teaching hospital in Toronto, Ontario, Canada. Participants included any patient either completing a formal written request or undergoing a MAID assessment.

Data collected included basic demographics, primary diagnosis relevant to MAiD request, location of MAiD request (outpatient, acute care inpatient or Palliative Care Unit (PCU) inpatient), Palliative Performance Scale (PPS) at the time of first assessment, palliative care involvement (as an outpatient, inpatient in acute care or in the PCU), and outcome of the MAID request (including whether the 10-day reflection period was shortened).

Statistical Analysis:

Demographic variables were analyzed with descriptive statistics.

To determine potential predictors of a shortened reflection period, logistic regression analyses (SAS version 9.4 for Windows) were performed to test for association between the clinical risk factors (age, location of MAiD request (inpatient/outpatient), PPS, diagnosis (malignant/non-malignant) and prior palliative care contact) and the outcome (shortened wait time, loss of decisional capacity or death). Given the goal of identifying risk factors for patients at risk of losing capacity in the 10-day wait period, the study groups for regression analysis were defined as all patients who received MAiD after completing the 10-day wait period (Group 1) as compared to those who either lost capacity or died prior to provision of MAiD (but who had a MAiD date established) combined with those who had the wait period shortened by the assessors (Group 2) (see Figure 1).Statistical significance was set at $p \leq 0.05$.
Receiver Operating Characteristic (ROC) curves were generated to further examine the relationship between PPS and risk of loss of capacity.

Ethics approval:

This study was approved by the Research Ethics Board at Sunnybrook Health Sciences Centre.

Results:

Between June 17, 2016 and April 30, 2019, a total of 155 formal requests for MAiD assessments were received. Of these, 141 patients were deemed eligible and 117 patients went on to receive MAiD. Of the cohort eligible for MAiD, 18 patients died or lost capacity to provide informed consent during the 10-day reflection period and 49 patients had the reflection period shortened, all due to risk of imminent loss of capacity though some were simultaneously felt at imminent risk of death (Figure 1).

Demographics are shown in Table 1. Logistic regression analysis found that lower PPS score was associated with shortening the 10-day reflection period, or losing capacity or dying within the 10-day waiting period (OR 0.850, 95% CI *0.803 - 0.900,* p<0.0001). Palliative care involvement was also associated with shortening the reflection period, losing capacity, or dying before the 10-day reflection period was over (OR 8.984, 95% CI 1.128 - 71.563, p=0.038) (Table 2). PPS distribution between the groups is demonstrated in Figure 2, with a skewed distribution towards lower PPS values in Group 2 versus Group 1.

Using ROC curves, the model optimizing both sensitivity and specificity was a PPS of 30% (Table 3, Figure 3).

Interpretation:

Our study identified predictors of shortening the 10-day reflection period or losing capacity prior to completion of the 10-day waiting period among MAID requesters at our hospital. PPS was found to be the strongest predictor with prior palliative care involvement also a statistically significant risk factor. Given many jurisdictions internationally have mandated wait periods, these findings may provide guidance to practitioners in assessing and following those patients requesting assistance in dying.

Comparable to the Canadian legislation, mandatory wait times are found in assisted dying legislation elsewhere in the world. In Victoria, Australia, the Voluntary Assisted Dying Act indicates that the shortest time from first physician assessment to administration of medication is 10 days (16), though this can be shortened if both assessors agree that the patient is at risk of imminent death. Similarly, in eight of nine U.S. states (and the District of Columbia) in which aid in dying is legal, there is a 15 day wait period between first and second oral requests, and a further 48 hours wait between receipt of written request and authorization of prescription by a physician (17). Belgian euthanasia law requires a wait period of "at least one month between the written request and the performance of euthanasia in situations where death is not imminent" (18). However, advance directives in Belgium are also permitted, though only in the instance of a patient who has become unconscious at the time of euthanasia.

Previously published findings both from our group and others (10, 19,20), suggest that a request for MAiD is a reflection of an individual's longstanding personality characteristics, their worldview and lifelong values. Individuals accessing MAiD strongly desire control over the conditions of their end of life care and place enormous importance on autonomy, independence, and a sense of self (20,21). For many of these patients, the possibility of being denied access to MAID due to loss of capacity is tremendously distressing, to the point that some will forego adequate symptom management to ensure medications do not interfere with capacity (22). The challenge lies in identifying which patients appropriately merit exclusion from the mandated wait period while still respecting the legislative safeguards.

The vast majority of our cohort (>90%) had palliative care involvement at the time of signing their request, a statistic similar to other jurisdictions (23,24). Palliative care contact was a significant predictor that either wait time was shortened or that the patient lost capacity or died prior to MAiD. Such involvement may reflect patients already later in the disease trajectory, or with more aggressive disease and significant symptom burden.

Three quarters of our patient cohort had a primary diagnosis of malignancy which we had anticipated being associated with greater risk of early loss of capacity given the risk such patients carry of precipitous decline from intercurrent events and complications. In comparison, patients with non-malignant disease often live for longer periods despite significant disability. We did not find, however, that diagnosis (as the binary division of malignant versus non-malignant) was a significant predictor. This may be explained in part by recognizing that for both groups, decision making about end of life planning and goals may have been left to very late stages of illness, specifically at the time of an acute decline, as opposed to being addressed earlier in the trajectory of disease.

Similarly, location of request was not a significant predictor of shortening of wait period or loss of capacity on regression analysis despite our finding that 91% of patients in Group 2 were inpatients at the time of their MAiD request. We had anticipated that those making a MAiD request as an inpatient would be at greater risk, reflecting the acuity of their illness. Conversely, we anticipated those requesting MAiD while at home would represent a more stable population, less likely to lose capacity. On further analysis, we noted that only when PPS was removed from the logistic regression analysis did location of request become significant, instead highlighting the importance of PPS.

PPS has previously been demonstrated as an independent predictor of mortality in different healthcare settings, with lower PPS scores indicating poorer function and shorter overall survival times (25-29). We observed a skewed distribution of PPS (Figure 2) between Group 1 (median PPS 50%) and Group 2 (median PPS 30%). Although it is sometimes possible to predict a patient's imminent loss of capacity and the need for urgent MAiD provision at the time of first assessment, in our cohort there were many patients for whom we did not anticipate this need initially. Specifically, of the 67 patients in Group 2 only 35 (52%) were identified in the original assessment as clearly requiring shortening of their 10-day wait period. Further analysis of the 18 patients who lost capacity or died prior to MAiD provision again showed a median PPS of 30% (range 20-50) as compared to the higher median PPS in Group 1. To ensure delayed

assessment was not a factor in this group, we noted the time from completion of the formal written request to time of first assessment. As shown in Table 1, the median time between request and assessment was 0 days for Group 2, and for the subset who lost capacity or died, the median was 0.5 days with 12 of 18 patients assessed within 24 hours of request. Attention to PPS at the time of the initial request may highlight patients more vulnerable to rapid decline and in need of regular surveillance, to reduce the chances of subsequent loss of capacity and therefore the option of MAiD.

The ROC curve for PPS indicates that if sensitivity and specificity are equally important, a PPS value of 30% would be the key cut point (distance to (0,1) = 0.33). However, given the crucial importance of capturing the window for access to MAiD in these patients, we propose that the sensitivity of the test criteria carries greater importance over specificity. A PPS of 40% as a cut point for identifying at-risk patients offers greater sensitivity (0.91, Table 3), while still remaining proximal to (0,1), distance = 0.35. As such, we propose utilizing a PPS value of 40% or under at the time of first assessment as a marker for patients at high-risk of early loss of capacity or death.

With this knowledge in mind, we have adapted our institutional approach in order to mitigate the risk of patients losing capacity or dying prior to provision of MAiD, specifically when they have identified MAiD as being of high importance. For any patient with a PPS score ≤40% at the time of signing their MAiD request, the primary MAiD assessor follows the patient closely, usually with daily assessments, with the view to identifying any clinical deterioration. The patient and family are alerted at the outset of the high possibility that MAiD may need to proceed on an urgent basis. The vascular access team assesses the patient's venous access promptly to identify any patients with poor peripheral venous access who may therefore need a peripherally inserted central catheter organized. Pharmacy is notified early so that medication can be prepared with short notice if required. Finally, the unit's patient care manager and interdisciplinary staff are notified of the possibility of urgent MAiD provision, in order to allocate appropriate staffing for the procedure and post-procedure bereavement support.

Limitations:

The primary limitation of this study is that it included a predominately inpatient population and hence the results may not be generalizable to a largely outpatient population. Further, there are a very limited number of providers and assessors at our institution which may add individual bias to clinical decisions that would differ from other assessors. Similar analyses at other sites would be warranted to confirm or refute these findings.

Conclusion:

Patients whose PPS is 40% or below when they formally request MAiD should be followed vigilantly, and steps should be taken to allow for rapid provision of MAiD with a greater expectation of the requirement to shorten the 10-day wait period.

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Figure 1. Outcome of all referrals for assessment of eligibility for Medical Assistance in Dying over study period

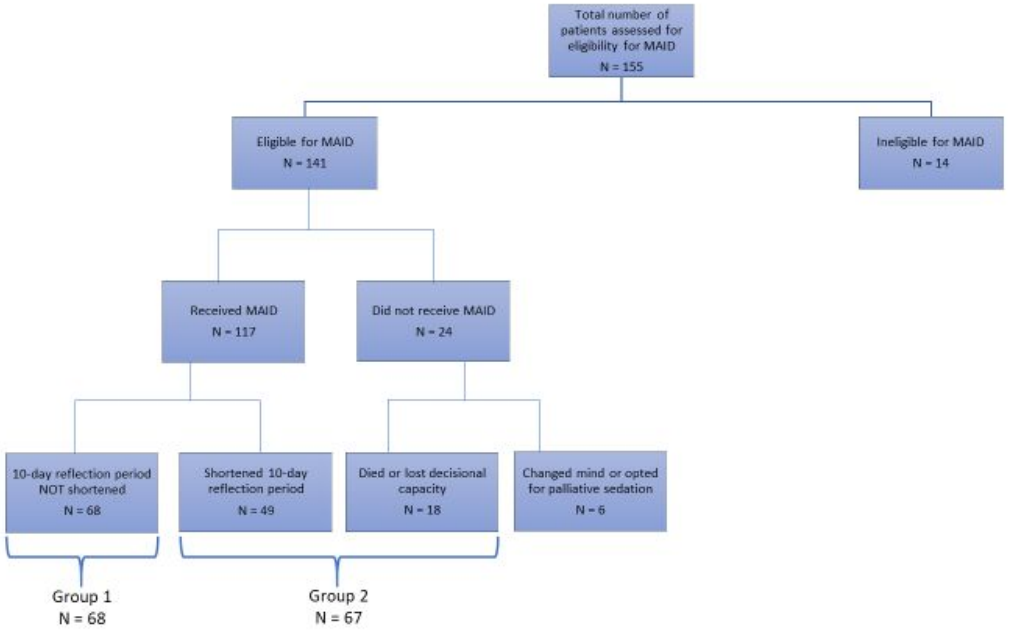


Table 1. Characteristics of patients who received MAiD without shortening of the 10-day wait period compared to patients with shortening of 10-day wait period, or who lost capacity / died

Variable	Patients who received MAiD without shortening of 10-day wait period Group 1	Patients who received MAiD but required shortening of 10-day wait period, or lost capacity / died Group 2
Total number	68	67
Median age (range)	72 (28-95)	75.9 (37-102)
Sex, n (%)		
Male	35 (51.5)	30 (44.8)
Female	33 (48.5)	37 (55.2)
Median PPS at time of written MAiD request (range)	50 (30-70)	30 (10-50)
Location of request, n (%)		
Inpatient	38 (56)	61 (91)
Outpatient	30 (44.1)	6 (9)
Diagnosis, n (%)		
Cancer	52 (76.5)	48 (71.6)
Other	16 (23.5)	19 (28.4)
Palliative Care contact prior to request, n (%)		
No	11 (16.1)	2(3)
Yes	57 (83.8)	65 (97)
Median number of days between written request and first assessment (range)	4 (-5 to 277)	0 (-3 to 82)

Figure 2. Distribution of PPS values for patients who lost decisional capacity or with shortened reflection period compared to those without shortening of reflection period

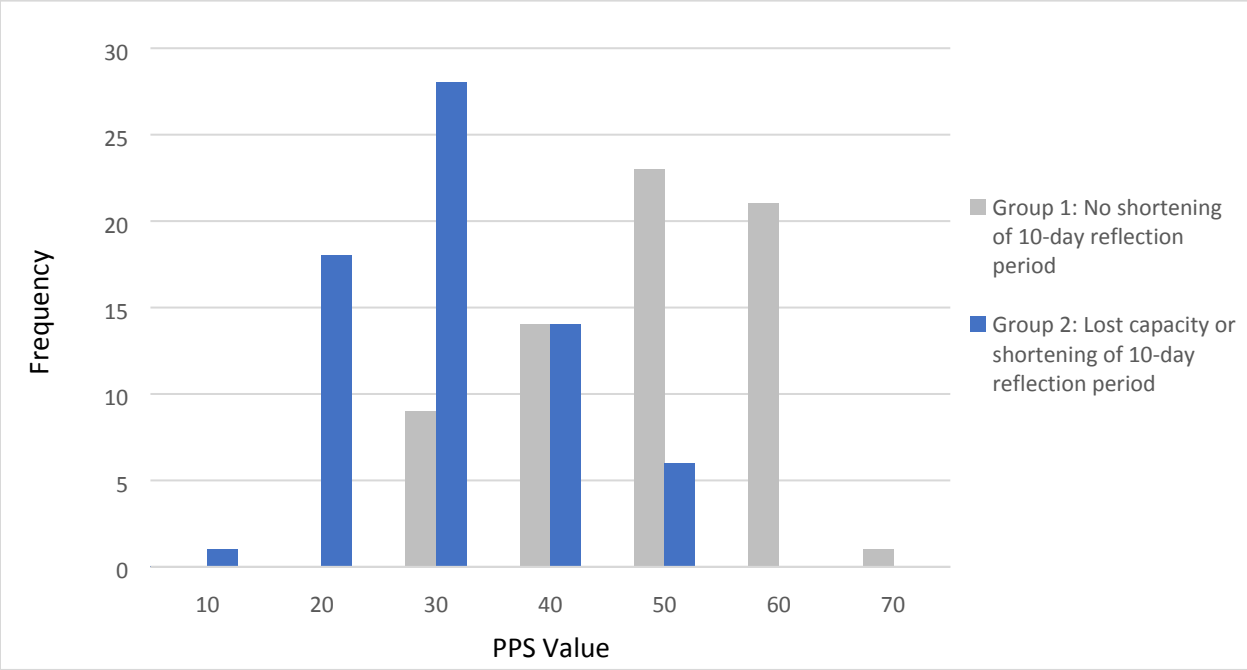
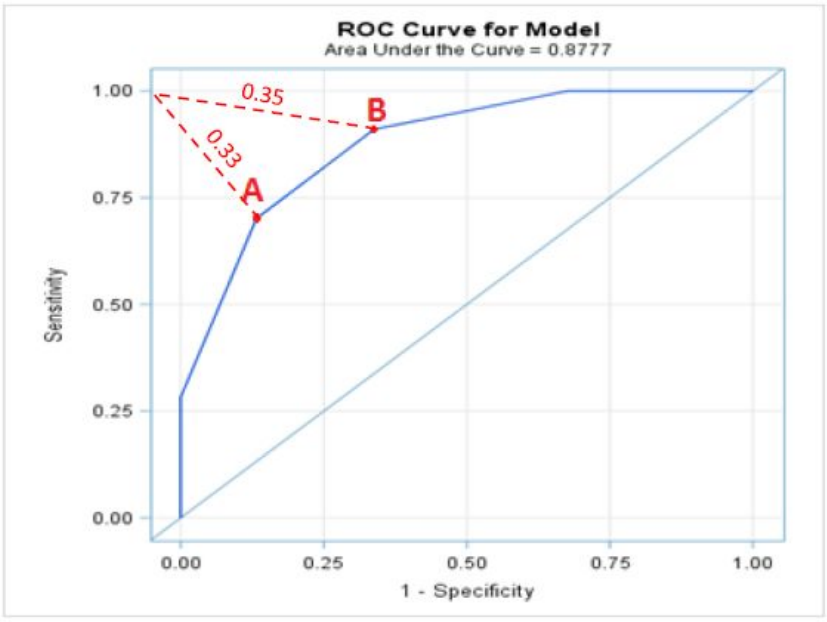


Table 2: Binomial Logistic Regression Analysis of potential risk factors for loss of decisional capacity, death or shortening of 10-day wait period for MAiD

Variable	Odds Ratio *(95% CI)*	p-values
Age	0.979 *(0.942, 1.017)*	0.2654
PPS	0.850 *(0.803, 0.900)*	<0.0001
Location patient signed written request	2.418 *(0.727, 8.044)*	0.1498
Diagnosis	1.065 *(0.284, 3.991)*	0.9253
Palliative Care contact	8.984 *(1.128, 71.563)*	0.0381

Figure 3. Receiver Operating Characteristic Curve for Palliative Performance Scale



Point A: PPS cut-point 30%. The 'optimal' cut-point is the point closest to (0, 1) on the ROC curve, hence 30% is the optimum.

Point B: PPS cut-point 40%. The second most optimal cut-point on the ROC curve and gives greater sensitivity than point A.

Table 3. Sensitivity and specificity levels by cut points (n= 135)

Obs	Sensitivity	1-Specificity	Specificity	Cut point	Distance from (O,1)
1	0.01493	0.00000	1.00000	10.0025	0.98507
2	0.28358	0.00000	1.00000	20.0048	0.71642
3	0.70149	0.13235	0.86765	30.0070	0.32653
4	0.91045	0.33824	0.66176	40.0093	0.34989
5	1.00000	0.67647	0.32353	50.0116	0.67647
6	1.00000	0.98529	0.01471	60.0139	0.98529
7	1.00000	1.00000	0.00000	70.0162	1.00000
8	1.00000	1.00000	0.00000	39.4898	1.00000

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1 2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4
Bias	9	Describe any efforts to address potential sources of bias	n/a
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed (*e*) Describe any sensitivity analyses	4
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	5 Fig 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	Table 1
Outcome data	15*	Report numbers of outcome events or summary measures over time	5 Fig 1

Table 1

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	5
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	5
Discussion			
Key results	18	Summarise key results with reference to study objectives	5, 6, 7
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	9
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	7, 8
Generalisability	21	Discuss the generalisability (external validity) of the study results	9
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	n/a

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.