ARTICLE

Portrait of driving practice following a mild stroke: a secondary analysis of a chart audit

Marie-Andrée Ouellet\textsuperscript{a,b}, Annie Rochette\textsuperscript{a,b}, Carole Miéville\textsuperscript{c}, and Lise Poissant\textsuperscript{a,b}

\textsuperscript{a}Occupational Therapy Program, School of Rehabilitation, University of Montreal, Montreal, Canada; \textsuperscript{b}Centre for Interdisciplinary Research in Rehabilitation in greater Montreal (CRIR), Montreal, Canada; \textsuperscript{c}Quebec Rehabilitation Research Network (REPAR), Montreal, Canada

ABSTRACT

Background: The majority of individuals who have had a mild stroke are discharged home from acute care. Yet, the proportion who are assessed for driving ability and given related recommendations is unknown.

Objective: To describe acute care practice related to driving among individuals whose discharge location is home.

Methods: A secondary analysis of data from a chart audit was realized in the Province of Quebec, Canada. Data were retrieved from the charts by trained extractors. Evaluation practice was described according to whether the driving assessment was specific or nonspecific to driving (cognitive, perceptual and visual functions). Descriptive statistics were used.

Results: The sample consisted of 419 charts of individuals with a mean age of 70.5 ± 13.3 years old. Mean length of hospital stay was 10.3 ± 13.3 days. Specific driving assessment was documented among 26/419 (6.2%) charts while for seven of these, the assessment was considered full. Meanwhile, 92/419 (22.0%) were considered as problematic for driving a vehicle. Nonspecific driving assessment was documented among 70/419 (16.7%), 43/419 (10.3%) and 33/419 (7.9%) of charts for cognitive, perceptual and visual functions, respectively. Charts were characterized by several missing data relating to driving.

Conclusion: The proportion of charts documenting driving restriction post-stroke in acute care was very low. Assuming that all driving discussions and referrals were captured in the charts (which may not be the case), our results would indicate an important gap in acute care practice as compared to best practices relating to driving post-stroke.

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Introduction

A significant proportion of stroke survivors return home quickly, particularly those with mild strokes, who alone account for nearly 60% of cases.\textsuperscript{1} Length of hospital stay is relatively short leaving modest time for a thorough rehabilitation assessment of potential restrictions in participation of individuals who can manage basic activities of daily living. Indeed, once back home, individuals with few functional deficits at first glance may experience a multitude of restrictions in their participation in several complex activities, such as working, doing leisure, maintaining satisfactory relationships or driving.\textsuperscript{2} Driving is one of the key elements of optimal participation, being a prerequisite hierarchically to accomplish other activities and roles outside of the home similarly to walking capacity, mood, and social support.\textsuperscript{3} Driving is especially a meaningful activity and questioning one’s ability to drive is susceptible to cause strong feelings and reactions.\textsuperscript{4} A prospective study conducted by Finestone and its collaborators\textsuperscript{5} with 53 participants who had had a stroke showed that driving is a productive activity that promotes full participation and integration in the community. However, in terms of body functions, a person who survives a stroke may have several disabilities, including mental, sensory, neuromusculoskeletal and motion-related impairments\textsuperscript{6} that may affect driving performance. More specifically, disabilities may be related to visual-spatial perception, attention, sensation, reaction time, vision or muscle strength.\textsuperscript{7} In short, all these factors can have an impact on the
ability to drive a car safely and therefore lead to a limitation of activity.

Several pre-driving assessments have demonstrated good validity and relevance for clinical use with stroke patients. Indeed, Devos and collaborators\textsuperscript{8} concluded that the Road Sign Recognition Test, the Compass and the Trail Making Test B (TMT B) identify drivers at risk of failing a road test with an accuracy corresponding to 84\%, 85\%, and 80\%, respectively. Furthermore, Marshall and colleagues\textsuperscript{9} demonstrated that Trail Making Test A and B (TMT A and TMT B) and Taylor Complex Figure Design as well as Useful Field of View Test (UFOV) and Motor-Free Visual Perception Test (MVPT) are the most predictive nonspecific driving assessments. Finally, the Montreal Cognitive Assessment\textsuperscript{10} can be a rapid screening tool to be administered in a clinic to assist professionals in making decisions related to the need for a more thorough driving assessment: the threshold score ≤ 11/30 indicates a high risk of failing a road test and a score between 12 and 27 implies a 50\% risk of failure on the same test.\textsuperscript{11} The driving-specific assessment tools that have demonstrated good validity, reliability, and ease of use with an older clientele and were recommended consisted of the Cognitive Behavioral Driver’s Inventory (CBDI), DriveABLE Competence Screen, UFOV and Stroke Driver Screening Assessment (SDSA).\textsuperscript{12}

Meanwhile, national\textsuperscript{13} and International (National Transport Commission, 2017)\textsuperscript{14–16,19} practice guidelines recommend driving cessation for a minimum of 1 month following a stroke given the risk of recurrence during this period. In Canada, one should not resume driving until a comprehensive neurological assessment has been performed.\textsuperscript{13} More specifically, in Quebec, all drivers are required to report any change in their physical or mental condition that may affect their driving ability. They are required to consult their physician, who may also recommend a driving ability assessment by an occupational therapist. In fact, following a stroke, even a mild one, the person may overestimate their driving abilities and may not be fully aware of the impact of early re-driving, thus not reducing their exposure to driving after the incident.\textsuperscript{18} Following this one-month period, it is recommended\textsuperscript{13} that people who wish to drive again take part in screening (nonspecific off-road driving assessments), preferably by an occupational therapist, using a valid and reliable method, for any residual sensory, motor or cognitive deficits. All occupational therapists in Quebec are trained to perform these off-road assessments while a specific training is required to realize an on-road assessment\textsuperscript{20} in the presence of any residual deficits relating to driving, a full comprehensive evaluation (specific to driving), including an on-road assessment, is recommended.\textsuperscript{13} It is therefore essential for clinicians to inform patients before being discharged from acute care and make them aware of the recommendations.

According to a retrospective study of medical records on physicians’ compliance with regulations and carried out in typical medium to large-sized hospital in Sweden (n = 342 stroke incidents in 1 year), only 19\% of medical records had a written note about driving cessation post-stroke.\textsuperscript{21} Similarly, only 9\% (15/166) of patients surveyed in the United Kingdom reported that they had been informed of contraindications to driving before being assessed.\textsuperscript{22} According to a telephone survey of 480 Canadian occupational therapists providing rehabilitation services to stroke patients, 20\% of clinicians who practice inpatient and 34\% who work in the community would see driving as problematic following a stroke and those who reported on typically using a driver-specific assessment would be in the order of 12\%.\textsuperscript{23} In an attempt to explain this phenomenon, the authors made the assumption that setting priorities relating to what to assess, along with lack of time and pressure to free beds in acute care settings, might partially explain that low prevalence. Finally, it is important to consider that although all patients receive medical care following a stroke, not all are seen by an occupational therapist before discharge. This can therefore influence the management and transmission of significant driving information given to patients.\textsuperscript{18}

**Objectives**

The objectives of this study were to describe acute care practice in Quebec, Canada relating to specific and nonspecific driving assessments for clients with stroke whose discharge location is home (typically mild stroke) and document the proportion of charts with a reference for post-discharge outpatient services or driving recommendations.
Methods

Study design

This study consists of a secondary analysis of data from a chart audit that was conducted for a major research project entitled Partnerships for Health System Improvement (PHSI) – Toward a Continuum of Services for Stroke: Evaluation of Rehabilitation Services Structures, Processes and Performance Indicators in the province of Quebec, Canada. This manuscript was written to conform to the STROBE guidelines.

Population

All medical charts across 13/17 administrative regions were audited and included for adults with a primary diagnosis of stroke (excluding transient ischemic attack; ICD-10 codes G08, H34.0, H34.1, I60, I61, I63, I64, and I67.6) between 1 April 2012 and 31 March 2013 (n = 1 698 files). The results of the actual study focused on a sub-sample of the PHSI audit: only individuals who were discharged home from the acute care hospital (including emergency) were included. Since this study focused exclusively on stroke cases returning home, all these cases were studied, regardless of age, gender or location of the stroke.

Data collection

A file containing all the audit data organized according to the International Classification of Functioning, Disability and Health (ICF) was made available for purposeful sampling to select the variables to be used. Data relating directly to driving, i.e. the presence of a note in the chart regarding driving assessment, or indirectly relating to driving, i.e. the assessment of cognitive, perceptual or visual functions and the professional involved in each case were retrieved. In addition, all references made at discharge, recommendations, and education on resuming driving, as well as the sending of a notice to the driving regulatory body, if applicable, were also retrieved. Socio-demographic characteristics (age, gender, administrative region, marital status, presence or not of a caregiver at home); their main pre-stroke occupation; the type and location of stroke and the pre-stroke lifestyle were also retrieved for sample description. Finally, ethical approval was obtained by the team of researchers in charge of the initial charts’ audit.

Statistical analysis

IBM SPSS Statistics version 25 for MAC software was used. Descriptive statistics were used to describe the sample. The results were reported in terms of frequencies and percentages; mean and standard deviation was also calculated for age, the only continuous variable. A two-level distinction was considered, namely, identifying those who have undergone driver-specific assessment (Dynavision, Color Trails Test, Useful Field of View Test, DriveABLE or Elemental Driving Simulator) and those who have undergone screening/assessment of cognitive, perceptual and visual functions, nonspecific to driving. Files with undocumented data were recoded as missing data.

Results

Sample description

Of the 1 698 files that were audited for the PHSI, 420 met the inclusion criteria of being discharged home from acute care (including emergency). An outlier for a length of stay of 734 days was excluded from the analyzes for a subsample of n = 419 for this study. The average length of stay in acute care was thus 10.3 ± 13.3 days with a mode and median of 2 and 7 days, respectively, and a range from 0 days (a person only went through the emergency room without being hospitalized) to 133 days. The average age was 70.5 years, ranging from 20 to 96 years, of which 59.4% (249/419) were male and 43.0% (180/419) were retired before the stroke (see Table 1). More than half, or 58% (243/419), were either married or common-law partner and 42.0% (176/419) lived in a house. With respect to their arrival in acute care, most were referred by ambulance services (39.4%; 165/419) or presented themselves to the emergency room (35.3%; 148/419). The type of stroke was ischemic for the majority (77.1%; 323/419) and side of stroke was left in 47.0% (197/419) of cases and right in 40.3% (169/419). Finally, with
respect to driving, more than half (52.0%; 218/419) of the files had missing information regarding the pre-stroke driving habit, while 41.1% (172/419) were considered independent drivers without technical assistance and 6.9% (29/419) were described as non-drivers before the stroke (Table 1).

Residence prior to stroke was predominantly outside the metropolitan area (Table 2). In 93.8% of cases, home was the discharge destination recommended by the health-care team, in line with the destination chosen by the user on discharge. However, a small proportion of cases returned home directly from acute care, while a transfer to an inpatient rehabilitation facility (2.6%) or to long-term care (0.7%) was recommended by the health-care team (Table 2).

Driving assessments

Driver-specific assessments were partially documented in 19/419 charts (4.5%) and documented in full for seven of them (1.7%) (Table 3). In 6/7 cases (85.7%), the occupational therapist was the professional who completed this assessment. For the three categories nonspecific to driving, the Mini Mental State Examination (MMSE or Folstein Test), the Bell’s Test and the Visual Field Assessment were the assessments more frequently completed in full (Table 3). Cognitive and perceptual functions were assessed by an occupational therapist in 64/70 cases (91.4%) and 42/43 cases (97.7%) respectively. Visual functions (visual field evaluation) were assessed mainly by a physician (17/33; 51.5%) or a physiotherapist (13/33; 39.4%).

Table 1. Socio-demographic characteristics (n = 419).

| Age at stroke (years) | Mean (standard deviation) |
|-----------------------|---------------------------|
|                       | 70.5 (13.3)               |

| Gender                | Frequency (%) |
|-----------------------|---------------|
| Man                   | 249 (59.4)    |
| Woman                 | 170 (40.6)    |

| Marital status        | Frequency (%) |
|-----------------------|---------------|
| Married or common law | 243 (58.0)    |
| Widowed               | 66 (15.8)     |
| Single                | 38 (9.1)      |
| Divorced or separated | 35 (8.4)      |
| Missing               | 37 (8.8)      |

| Type of stroke         | Frequency (%) |
|------------------------|---------------|
| Ischemic               | 323 (77.1)    |
| Intracerebral hemorrhage | 31 (7.4)    |
| Subarachnoid hemorrhage | 17 (4.1)     |
| Missing                | 48 (11.4)     |

| Side of stroke         | Frequency (%) |
|------------------------|---------------|
| Left                   | 197 (47.0)    |
| Right                  | 169 (40.3)    |
| Bilateral              | 10 (2.4)      |
| Missing                | 43 (10.3)     |

| Type of residence before stroke | Frequency (%) |
|---------------------------------|---------------|
| Single-family house, semi-detached, town house | 176 (42.0) |
| Apartment/Condominium           | 101 (24.1)   |
| Private residence for the elderly | 59 (14.1)    |
| Other                            | 11 (2.6)     |
| Low-cost housing                 | 2 (0.5)      |
| Missing                          | 70 (16.7)    |

| Provenance                     | Frequency (%) |
|---------------------------------|---------------|
| Ambulance services              | 165 (39.4)    |
| Ambulant (by himself)           | 148 (35.3)    |
| Hospital or rehabilitation center | 74 (17.7)    |
| Other                           | 12 (2.9)      |
| Missing                         | 20 (4.8)      |

| Main occupation before stroke  | Frequency (%) |
|---------------------------------|---------------|
| Retired                         | 180 (43.0)    |
| At work                         | 83 (19.8)     |
| Unemployed                      | 21 (5.0)      |
| Other (e.g. volunteer, schooling, sick leave) | 24 (5.7) |
| Missing                         | 111 (26.5)    |

| Pre-stroke Driving habit        | Frequency (%) |
|---------------------------------|---------------|
| Driving a car (independent without technical assistance) | 172 (41.1) |
| Did not drive a car (dependent on others) | 29 (6.9)    |
| Missing                         | 218 (52.0)    |

Table 2. Continuum of care from admission to discharge (n = 419).

| Place of residence | Frequency (%) |
|--------------------|---------------|
| Western and Northern Quebec | 186 (44.4) |
| Eastern Quebec      | 123 (29.4)   |
| Montreal Metropolitan Area | 110 (26.3) |

| Recommended destination at discharge | Frequency (%) |
|--------------------------------------|---------------|
| Home address of origin               | 393 (93.8)    |
| With outpatient rehabilitation       | 116 (27.7)    |
| With home care services              | 56 (13.4)     |
| Transfer to an institution for internal rehabilitation | 11 (2.6) |
| Other residence (moving)             | 4 (1.0)       |
| With outpatient rehabilitation       | 1 (0.2)       |
| With home care services              | 2 (0.5)       |
| Long-term care                       | 3 (0.7)       |
| Other                                | 8 (2.0)       |

| Other | Frequency (%) |
|-------|---------------|
| Outpatient rehabilitation           | 111 (26.5)    |
| Home care                          | 102 (24.3)    |
| Occupational therapy               | 29 (6.9)      |
| Physiotherapy                       | 23 (5.5)      |
| Nursing care                        | 39 (9.3)      |
| Social worker                       | 26 (6.2)      |
| Other                               | 18 (4.3)      |
| Other                               | 32 (7.6)      |
| Driving assessment                  | 4 (1.0)       |
| Community resources                 | 2 (0.5)       |
| Smoking Cessation Program           | -             |
| Conditioning program                | -             |
| Self-management/empowerment program | -             |
| Secondary Prevention Clinic         | -             |
| Center for Visual Rehabilitation    | -             |
Overall, 135/419 charts (32.2%) explicitly mentioned either a problem concerning driving (92/419; 22%) or no issue with driving abilities (43/419; 10.2%), while 284/419 (67.8%) did not include any comments on this subject (Table 3).

Post-discharge references and driving recommendations

The main references at discharge (Table 2) were external rehabilitation (26.5%) and/or home support services (24.3%) but not necessarily with a driving recommendation. Four out of 419 charts (1.0%) had a note indicating that a specific reference had been made for a more thorough assessment of driving. A recommendation on driving was found in 78/419 (18.6%) of charts. More specifically, 23/419 (5.5%) of charts included a note about providing information on driving after stroke, transmitted in 69.6% of cases by an occupational therapist. Finally, a notice was sent to the provincial driving regulatory body for 21/419 users (5.0%), by a physician or specialist in 63.6% of cases (Table 4).

Discussion

The objective of this study was to describe acute care practice in Quebec, Canada in relation to assessment of driving for clients who are discharged home (typically mild stroke) as well as to document the proportion of cases with a reference for post-discharge outpatient services and recommendations relating to driving.

Specific driving ability assessment and recommendations

Our results indicate that both pre-stroke driving habits and post-stroke driving ability were very poorly documented in acute care settings among patients who are returned home quickly. In addition, only half of the charts mentioned a reference to post-discharge outpatient services upon return home including only 4/419 referred for a specific driving assessment. Since driving is contraindicated for at least 1 month following a stroke, this may explain why driving is not addressed outright, at least in an acute care setting. However, our results indicate that even this recommendation of not driving for 1

| Table 3. Driving assessments and limitations documented in charts (n = 419). |
| --- |
| **Assessments specific to driving*** | **Frequency (%)** |
| Completed in full | 7 (1.7) |
| Partially completed | 19 (4.5) |
| Missing information | 393 (93.8) |

**Assessments nonspecific to driving completed in full**

| Cognitive functions | **Frequency (%)** |
| --- | --- |
| Canadian Neurological Scale (CNS) | 15 (3.6) |
| National Institutes of Health Stroke Scale (NIHSS) | 2 (0.5) |
| Loewenstein Occupational Therapy Cognitive Assessment (LOTCA) | – |
| Mini Mental State Examination (MMSE) or Folstein Test | 70 (16.7) |
| Modified Mini Mental State Examination (3MS) | 5 (1.2) |
| Montreal Cognitive Assessment (MoCA) | 46 (11.0) |
| Elderly Cognitive Testing Protocol (PECPA-2r) | 12 (2.9) |
| Rivermead Behavioral Memory Test (RBMT) | 1 (0.2) |
| Clock drawing test | 37 (8.8) |
| Trail Making Test (TMT A and B) | 11 (2.6) |
| Wisconsin Card Sorting Test (WCST) | – |
| Profile of ADLs – Task 14: Driving a Vehicle | – |

**Perceptual functions**

| **Frequency (%)** |
| --- |
| Interview with patient/family | 15 (3.6) |
| Albert’s test | – |
| Behavioral Inattention Test (BIT) | – |
| Line Bisection test | 3 (0.7) |
| Motor-Free Visual Perception Test (MVPT) | 17 (4.1) |
| Rivermead Perceptual Assessment Battery | – |
| Single Letter Cancellation Test (SLCT) | 3 (0.7) |
| Bell test | 43 (10.3) |
| Comb and razor test | – |

**Visual functions**

| **Frequency (%)** |
| --- |
| Interview with patient/family | 29 (6.9) |
| Snellen scale | – |
| Visual extinction assessment | 1 (0.2) |
| Visual field evaluation | 33 (7.9) |

**Driving a vehicle – Limitations**

| Problematic issues | **Frequency (%)** |
| --- | --- |
| Not problematic | 43 (10.2) |
| Missing | 284 (67.8) |

*Assessments considered specific to driving were: Dynavision, Color Trails Test, Useful Field of View Test (UFOV), DriveABLE, Elemental Driving Simulator (EDS)

Overall, 135/419 charts (32.2%) explicitly mentioned either a problem concerning driving (92/419; 22%) or no issue with driving abilities (43/419; 10.2%), while 284/419 (67.8%) did not include any comments on this subject (Table 3).

| Table 4. Driving recommendations documented in charts (n = 419). |
| --- |
| **Specific driving recommendation** | **Frequency (%)** |
| Documented | 78 (18.6) |
| Missing | 341 (81.4) |
| **Interventions specific to driving** | **Frequency (%)** |
| Documented | 26 (6.2) |
| **Discussion about driving with patient/family** | **Frequency (%)** |
| Yes, by Occupational therapist | 16 (69.6) |
| Physician | 7 (30.4) |
| **Notice sent to regulatory body on driving restrictions** | **Frequency (%)** |
| Yes, by Physician | 13 (63.6) |
| Occupational therapist | 7 (31.8) |
| Not specified | 1 (4.5) |
month was not captured systematically in the medical files for the majority. While one may argue that health professionals do not write everything in charts, driving is known to be a sensitive and safety issue which should not be overlooked.\textsuperscript{4,25} Moreover, an under-documentation cannot compensate fully these results as in a survey, only 9% (15/166) of patients reported having obtained information about driving a vehicle following a mild stroke.\textsuperscript{22} There is also reason to wonder whether patients who return home without a reference have access to medical follow-up to discuss driving at some point.\textsuperscript{21} Especially since in Quebec, the obligation to report on driving in discretionary.\textsuperscript{26} The avoidance of medically addressing the driving issue might also partially be explained by a lack of confidence. Indeed, 45% of family physicians in Canada (n = 205/448) said they are not very confident in administering driver-specific assessments and 88.6% (n = 400/452) perceive that they would benefit from additional training in the field.\textsuperscript{27} Given the context of health services in Quebec where a large proportion of the population does not have easy access to a family doctor and where there are waiting lists to receive outpatient services, our results are alarming.

Knowing that driving allows full participation in the community but can likely be influenced by the presence of post-stroke deficits, it is essential to address it as a priority in acute care before the individual is back home and may be inclined to drive again, not being aware of the contraindications in this regard. In fact, in a mixed-methods study of participation after a mild stroke, participants mentioned that they self-exposed themselves to driving shortly after leaving acute care in order to provide concrete proof of their own ability to drive a vehicle.\textsuperscript{2} We also know that drivers tend to overestimate their driving skills in the sense that they have a positive bias toward self as compared to their peers.\textsuperscript{28} Therefore, there is reason to be concerned about the insufficient level of knowledge of these patients leaving acute care regarding compliance with the recommendations if they have simply not been informed about them.

**Assessment of nonspecific driving ability**

A variety of tools were used to assess cognitive, perceptual and visual functions, most of the time by an occupational therapist, although there was no mention of these tools being used to assess specifically driving prerequisites. Besides those tools, the occupational therapist might have screened for residual deficits using a bottom-up approach\textsuperscript{29} that is direct observation while performing a meaningful activity which was not captured by the current audit. The MMSE being the one most frequently used is supported by the scientific literature as a screening tool\textsuperscript{30,31} although even after many years of research, the gold standard to assess fitness to drive remains the on-road assessment.\textsuperscript{9,32} The use of these tools in acute care might be relevant to screen the absence of residual deficits after a mild stroke in those functions required for driving. Nevertheless, even in the absence of deficits, because of the high risk of recurrence early on, a one-month driving cessation is recommended post-stroke.\textsuperscript{13} This might partially explain why the use of those tests remains low in acute care as they could be realized at one-month post-stroke, prior to resuming driving. Another issue lies in the fact that even in acute care, not all stroke cases are seen by an occupational therapist.\textsuperscript{18} Furthermore, most individuals with a mild stroke discharged home from acute care are not systematically referred to occupational therapy, and yet, the occupational therapist is the health professional better suited to assess driving ability.\textsuperscript{33}

**Strengths and limitations**

This study has some strengths and limitations that deserve to be addressed. First, the sample under study is composed of hundreds of files from 13/17 administrative region, which is large enough to be representative of the target population. This study improves the state of knowledge, particularly on driving practices in Quebec, among the population with a mild stroke, which is still poorly documented. However, the data were collected between 2012 and 2013, i.e. during the period preceding the gradual deployment of early supported discharge services in Quebec. Current practice may therefore be improved and hopefully better addresses the reality of mild stroke survivors. Finally, the large number of missing data could be due to the lack of rigor in record-keeping in the sense that clinicians may not write down in a central file everything that they do. Missing data could also be explained by inter-variability...
of auditors, despite training and monitoring by the research team.

**Conclusion**

One of the main objectives of this study was to document current practice in the management of driving ability for clients with a mild stroke who are discharged home from acute care. While we recognize the limitation of a chart audit as clinicians might do more than what they write in the charts, the large proportion of missing data makes us wonder if patients did get the right information about driving post-stroke. If not, they might resume driving in the presence of undetected residual deficits and increase the risk of a crash or equally problematic, they might not resume driving although they could which could then increase social isolation.

**Ethics approval**

Obtained for the original larger study entitled *Partnerships for Health System Improvement (PHSI) - Towards a Continuum of Services for Stroke: Evaluation of Rehabilitation Services Structures, Processes and Performance Indicators*

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### STROBE Statement – Checklist of items that should be included in reports of cross-sectional studies

| Item No | Recommendation |
|---------|----------------|
| **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 |
| **Introduction** | |
| Background/rationale | 2  
Explain the scientific background and rationale for the investigation being reported |
| Objectives | 3  
State specific objectives, including any prespecified hypotheses |
| **Methods** | |
| Study design | 4  
Present key elements of study design early in the paper |
| Setting | 5  
Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection |
| Participants | 6  
(a) Give the eligibility criteria, and the sources and methods of selection of participants |
| Variables | 7  
Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable |
| 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 |
| Bias | 9  
Describe any efforts to address potential sources of bias |
| Study size | 10  
Explain how the study size was arrived at |
| Quantitative variables | 11  
Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why |
| 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, describe analytical methods taking account of sampling strategy  
(e) Describe any sensitivity analyses |
| **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 analyzed  
(b) Give reasons for nonparticipation at each stage  
(c) Consider use of a flow diagram |
| 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 |
| Outcome data | 15*  
Report numbers of outcome events or summary measures |
| 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 |
| Other analyses | 17  
Report other analyses done – eg analyses of subgroups and interactions, and sensitivity analyses |
| **Discussion** | |
| Key results | 18  
Summarize key results with reference to study objectives |
| 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 |
| Interpretation | 20  
Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence |
| Generalizability | 21  
Discuss the generalizability (external validity) of the study results |
| **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 |

*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 www.strobe-statement.org.