RASSEGNE E ARTICOLI

Potentially inappropriate prescribing before and after nursing home admission: a retrospective observational study in a sample of Italian nursing homes

Potenziali prescrizioni inappropriate prima e dopo l'accesso nelle residenze sanitarie assistenziali: uno studio osservazionale retrospettivo su un campione di residenze sanitarie assistenziali italiane

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ABSTRACT

OBJECTIVES: to assess the occurrence of potentially inappropriate prescribing (PIP) in residents of Tuscany nursing homes (NHs) and its variation before and after NH entry.

DESIGN: retrospective observational study using data from the Regional Administrative Database of Tuscany.

SETTING AND PARTICIPANTS: the study involved residents of 67 Tuscan NHs identified between 2011 and 2012. To estimate PIP prevalence before and after NH, a subset of 10 indicators of the Screening Tool of Older Person's Prescriptions (STOPP) criteria were selected.

MAIN OUTCOME MEASURES: prevalence of PIP.

RESULTS: considering 2,801 NH residents, the proportion of PIP ranged from 0.0% to 55.2% and from 0.0% to 33.9% before and after the NH admission, respectively. Overall, this study showed a decrease in the occurrence of PIP after the NH admission for most of the indicators, reaching statistical significance for indicator 3 (tricyclic antidepressants in combination with an opiate or calcium channel blockers), 7 (prescription of NSAIDs in heart failure patients), and 9 (warfarin in combination with NSAIDs).

CONCLUSIONS: although the reduction of PIP after NH admission may suggest greater awareness about the appropriateness of drug use, more efforts still need to be made.

Keywords: pharmacoepidemiology, nursing homes, elderly, quality of care, inappropriate prescriptions

WHAT IS ALREADY KNOWN

- **The risk of drug-related negative outcomes is a relevant issue, especially in older persons.**
- **The risk of potentially inappropriate prescribing (PIP) is particularly high and worrisome in nursing home (NH) residents.**
- **Different criteria have been developed to define and identify PIP in elderly patients with the aim of reducing the use of medications with unfavourable benefit-risk ratio.**

WHAT THIS STUDY ADDS

- **A reduction in total number of PIP was observed after NH admission.**
- **However, the prevalence of PIP appears to be higher than expected, particularly for residents being prescribed with warfarin in combination with NSAIDs, and for residents prescribed with NSAIDs despite a diagnosis of heart failure.**
- **More efforts need to be made considering the persistence of PIP after NH admission.**

RIASSUNTO

OBIETTIVI: valutare la prevalenza di prescrizioni potenzialmente inappropriate (PPI) nei residenti di 67 residenze sanitarie assistenziali (RSA) Toscane e la relativa variazione prima e dopo l'accesso in RSA.

DISEGNO: studio osservazionale retrospettivo condotto utilizzando i dati raccolti nel database amministrativo delle Regione Toscana.

SETTING E PARTECIPANTI: lo studio ha coinvolto i residenti di 67 RSA toscane identificati tra il 2011 e il 2012. Per stimare la prevalenza di PPI nei tre mesi precedenti e successivi all'ingresso in RSA, è stato selezionato un cluster di 10 indicatori ricavati dai criteri STOPP.

PRINCIPALI MISURE DI OUTCOME: prevalenza di PPI.

RISULTATI: considerando 2.801 residenti, la prevalenza di PPI risultava compresa tra lo 0,0% e il 55,2% e tra lo 0,0% e il 33,9%, rispettivamente, nel periodo precedente e successivo all'accesso in RSA. Nel complesso, il presente studio ha messo in evidenza una diminuzione nella stima di prevalenza di PPI dopo l'entrata in RSA per la maggior parte degli indicatori selezionati, raggiungendo una variazione statisticamente significativa per l'indicatore 3 (antidepressivi triciclici in combinazione con un oppiaceo o bloccanti dei canali del calcio), 7 (farmaci antinfiammatori non steroidei – FANS – nei pazienti con scompenso cardiaco) e 9 (warfarin in combinazione con FANS).

CONCLUSIONI: sebbene la riduzione nella prevalenza di PPI dopo l'accesso in RSA possa suggerire una maggiore consapevolezza sull'appropriatezza d'uso dei farmaci, ulteriori sforzi devono ancora essere compiuti.

Parole chiave: farmacoepidemiologia, residenze sanitarie assistenziali, anziano, qualità delle cure, prescrizioni inappropriate

INTRODUCTION

Although the potential benefits of pharmacological therapy are unquestionable, the risk of drug-related negative outcomes is a relevant issue, mainly in older persons. Indeed, while polypharmacy increases the risk of drug-drug and drug-disease interactions,[1] age-related changes in several physiological characteristics, as well as chronic diseases, can affect drugs pharmacokinetics and pharmacodynamics,[2] leading to an increased risk of adverse drug reactions (ADRs).

Potentially inappropriate prescribing (PIP) is defined as the prescription of a medication that may increase the risk of an ADR in a specific population subset, eventually leading to hospitalization, morbidity, mortality, and disproportionate health care costs. Different criteria have been developed to define and identify PIP in elderly patients,[3,4] with the aim of reducing the use of medications with unfavourable benefit-risk ratio, especially when alternative and equally effective treatment options with lower risk of ADRs are available. Globally, there are two main types of validated tools that can be used in assessing prescriptive appropriateness. The former are represented by the Screening Tool of Older Person's Prescriptions (STOPP)/Screening Tool to Alert doctors to Right Treatment (START) criteria, and are generally applied in Europe to detect PIP and treatment omissions.[3] The latter are represented by the Beers criteria, a United States based tool constructed to identify medication problems in older patients.[4]

The risk of PIP is particularly high and worrisome in nursing home (NH) residents.[5] It is well known that most NH residents are generally exposed to a relevant number of pharmacological treatments to manage chronic multimorbidity and symptoms, thus increasing the risk of PIP. This last has been associated with poor clinical outcomes (i.e., ADRs, hospitalizations, death, etc.). Therefore, in the setting of NHs, efforts should be made to monitoring, and possibly preventing, PIP in this extremely vulnerable population.[6] In fact, the optimization of pharmacological treatment is crucial for the process of care in older individuals. In Italy, 25 NH beds per 1,000 older persons are estimated, with a mean number of drug prescriptions of more than 5 per patient.[7] A high likelihood of PIP can be anticipated in this setting, yet evidence on this issue is scarce. In this context, this study aimed to assess the prevalence of PIP and its variation from the pre-admission period in a sample of residents of Italian NHs. PIP was assessed according to a subset of 10 indicators derived from the STOPP criteria.[3]

METHODS

This retrospective observational study was part of the project "Monitoring the quality of care in nursing homes", coordinated by the Italian Ministry of Health, involving 67 NHs in the Tuscany Region (Central Italy), involving approximately 22% of all regional NHs, which offer residential care to disabled persons aged ≥65 years.

Data were obtained from the Regional Administrative Database of Tuscany, which includes different registries potentially linkable through a pseudo-anonymized personal identifier code. In particular, the following sources were used:

- the NH registry, which includes interventions, procedures and other data provided in the residential and semi-residential care setting and related to older or disabled subjects;
- the outpatient's drug dispensing registries, covering both drugs dispensed by pharmacies in the community and those distributed directly by hospital pharmacies;
- the hospital discharge records database, which included discharge diagnoses and procedures performed during hospitalization.

All patients institutionalized in NH in the period 2011-2012 were included in the study. To estimate PIP, a subset of indicators of the STOPP criteria was considered3 (Table 1). For each resident, the date of entry in the NH was considered as the index date, and a 3-month time period before and after the index date was evaluated to assess the risk of PIP before and after NH admission.

For each indicator, a specific PIP cohort was defined. For disease-related indicators (2, 4, 5, 6, 7, 8, 10), residents were defined as exposed to a PIP if they received at least one inappropriate medication in the 3-month time period before and after the index date. Residents were included in one or more PIP cohorts if they were affected by more than one disease of interest. Patients with an incident diagnosis of one or more disease of interest during the 3-month time period before or after the index date were excluded. For medication-related indicators (1, 3, 9), all residents exposed to at least one specific medication during the 3-month time period before and after the index date were selected.

Additional analyses were performed for indicators 4, 6, 7, and 8. As far as indicator 4, prevalence of PIP was re-estimated defining patients with Parkinson's disease based on levodopa prescription (ATC class: N04BA*). Similarly, for indicator 6, presence of glaucoma was defined based on anti-glaucoma drugs prescriptions (ATC class: S01E*). Concerning indicators 7 and 8, the most frequently prescribed nonsteroidal anti-inflammatory drugs (NSAIDs) were also detailed.

The prevalence of PIP before and after NH admission was estimated by dividing the number of residents with a PIP for the total number of residents included in the specific PIP cohort. Data are presented as numbers and percentages. The proportion of PIP before and after NH admission was compared with the Mc-Nemar test for paired data. Data analysis was performed using the software STATA 16.

The study was conducted according to the principles of the Helsinki Declaration and was approved by the Regional Committee for Bioethics of Tuscany Region and by the Ethics Committee of the Local Health Units of Siena, Florence, and Pisa (Tuscany Region).

RESULTS

During the 2-year study period, a total of 2,801 NH residents were included in the study. The cohorts in which the PIP indicators could be applied ranged from 41 to 937 participants. The prevalence of PIP ranged from 0.0% to 55.2% and from 0.0% to 33.9% before and after the NH admission, respectively (Table 1).

Pre-admission PIP prevalence reached figures as high as 55.2% for indicator 9 (warfarin in combination with NSAIDs), 50.9% for indicator 7 (prescription of NSAIDs in heart failure patients), and 37.5% for indicator 8 (prescription of NSAIDs in chronic renal failure patients). Post-admission PIP prevalence declined compared to pre-admission values for nine indicators, reaching statistical significance for indicators 3, 7, and 9. Conversely, a significant increase was observed only for indicator 5 (prescription of phenothiazines in subjects with a diagnosis of epilepsy).

For indicator 4, although at a non-statistically significant level, the use of neuroleptics in patients affected by Parkinson's disease decreased before and after the NH admission (from 10.1% to 5.0%, respectively). On the contrary, identifying patients with Parkinson disease based on the prescription of levodopa showed an increase in the proportion of patients with PIP. In fact, the prevalence of inappropriate medications doubled before admission (from 10.1% to 20.1%) and tripled after NH admission (from 5.0% to 17.5%). Similarly, as for as indicator 6, the use of nebulized ipratropium in patients affected by glaucoma decreased before and after the NH admission (from 4.8% to 52.4%, respectively), while identifying patients with glaucoma based on the prescription of anti-glaucoma drugs showed an increase in the proportion of patients with PIP (from 2.2% to 2.4% before NH admission and from 1.8% to 2.4% after NH admission). Concerning indicators 7 and 8, the most frequently prescribed NSAIDs were detailed in Table 1.

DISCUSSION

The prevalence of PIP significantly varied among the 10 criteria considered. According to several European studies referring to the use of STOPP and other comparable criteria (i.e., Norwegian General Practice-Nursing Home criteria, NORGEP-NH),5,8-10 the proportion of PIP resulted between 48% and 73% among elderly residents in NH. Even if a reduction in total number of PIP was observed, the proportions of patients with PIP after NH admission appear to be higher than expected, particularly for residents prescribed with warfarin in combination with NSAIDs, and for residents prescribed with NSAIDs despite a diagnosis of heart failure. Specifically, in a study performed in France and Belgium, Fournier and colleagues found that, after 8 months of follow-up, among the 218 NH residents included in the analysis there was a statistically significant reduction in the prevalence of PIP of 9.1%. They found a high reduction for proton pump inhibitors.[5] Another cross-sectional observational study conducted in Norway, researchers found that, among 881 patients from 30 NHs, 43.8% were prescribed at least one PIP, and 9.9% regularly received three or more PIPs. Moreover, females received more often than males at least one PIP.8 Schjøtt and Aßmus focused on inappropriate prescribing of psychotropic medications in Northern Europe NHs and found that psychotropic polypharmacy increased from 6.2% to 29.6% during the study period. While inappropriate psychotropic substances were reduced from 17.9% to 11.3%, potential inappropriate psychotropic combinations increased from 7.8% to 27.9% during the same time. Noteworthy, the increase in drug-drug interactions was associated with the PIP of antidepressants.[9] Using drug consumption data throughout a retrospective analysis, Cateau and colleagues evaluated the evolution of PIP in NHs of Western Switzerland. They computed the number of inappropriate defined daily doses per average resident (DDD/res) in each NH, observing that in 2018 the number of DDD/res was 7.3 and, of those, 2.2 were potentially inappropriate. Psycholeptics, psychoanaleptics, and antihypertenseives were the most inappropriate medications.[11]

According to the results of the present study, a reduction in the prevalence of PIP after NH admission was also found in another retrospective study aimed to compare the patterns of inappropriate prescriptions in community-dwelling older adults and in NH residents in Ontario (Canada). Although it is a non-European population, researchers found that PIP was less frequent in the NH than in the community setting.[12] In fact, adjusted analysis for age, sex, and comorbidity showed that NH residents were close to half as likely to experience a PIP as community-dwelling older adults.

The relatively high inappropriate prescription of NSAIDs showed in the present study is a well-known clinical issue.[13] Although the prevalence of PIP for indicator 7, 8, and 9 decreased after NH admission, the percentages were still too high. According to a large populationbased study, the prevalence of PIP during warfarin therapy ranged between 57% and 82%, and NSAIDs were the most common drugs involved.[14] This issue was also highlighted by another study, in which more than 16% of primary care

INDICATOR[a]	DEFINITION	BEFORE NH ADMISSION PREVALENCE (%)	AFTER NH ADMISSION PREVALENCE (%)	P-VALUE	ADDITIONAL ANALYSIS	
Risk of symptomatic heart block	Beta-blockers in combination with verapamil	5/374 (1.3)	2/374 (0.5)	0.257	–	
Risk of bronchospasm	Non-cardioselective beta-blockers in patients with COPD	1/166 (0.6)	0/166 (0.0)	0.317	–	
Risk of severe constipation	TCA in combination with an opiate or CCBs	45/937 (4.8)	12/937 (1.2)	**<0.001**	–	
Likely to worsen extra-pyramidal symptoms	Long-term neuroleptics (>1month) in patients with Parkinson's disease	6/59 (10.1)	3/59 (5.0)	0.083	Patients' definition based on levodopa prescription: • prevalence before NH admission 10.1%-20.1%; • prevalence after NH admission 5.0%-17.5%	
May lower seizure threshold	Phenothiazines in patients with epilepsy	7/66 (10.6)	15/66 (22.7)	**0.021**	–	
May exacerbate glaucoma	Nebulised ipratropium with glaucoma	2/41 (4.8)	1/41 (2.4)	0.564	Patients' definition based on anti-glaucoma drugs prescriptions: • prevalence before NH admission 2.2%-2.4%; • prevalence after NH admission 1.8%-2.4%	
Risk of exacerbation of heart failure	NSAIDs in patients with heart failure	83/163 (50.9)	45/163 (27.6)	**<0.001**	**Before NH admission:** 30.0% M01AB* 25.1% M01AE* 10.4% M01AC* 7.9% M01AH*	**After NH admission:** 13.4% M01AB* 12.8% M01AE* 4.9% M01AC* 2.4% M01AH*
Risk of deterioration in renal function	NSAIDs in patients with chronic renal failure	21/56 (37.5)	19/56 (33.9)	0.670	**Before NH admission:** 21.4% M01AB* 19.6% M01AE* 8.9% M01AH* 5.3% M01AC*	**After NH admission:** 21.4% M01AB* 17.8% M01AE* 3.5% M01AH* 1.7% M01AC*
Risk of gastrointestinal bleeding	Warfarin in combination with NSAIDs	68/123 (55.2)	27/123 (21.9)	**<0.001**	**Before NH admission:** 30.0% M01AE* 29.2% M01AB* 11.3% M01AH* 6.5% M01AC*	**After NH admission:** 11.3% M01AB* 9.7% M01AE* 2.4% M01AC* 1.6% M01AH*
Risk of acute exacerbation of glaucoma	Bladder antimuscarinic drugs in patients with glaucoma	0/41 (0.0)	0/41 (0.0)	–	–	

[a] STOPP/START criteria for potentially inappropriate prescribing in older people: Version 1.3 / *Criteri STOPP/START per prescrizioni potenzialmente inappropriate in persone anziane: versione 1.3*
ATC: anatomical therapeutic chemical classification system / *sistema di classificazione anatomico, terapeutico e chimico*
CCBs: calcium channel blockers / *calcio antagonisti*
COPD: chronic obstructive pulmonary disease / *broncopneumopatia cronica ostruttiva*
ICD-9: international classification of diseases, 9th version / *classificazione internazionale delle malattie, 9a versione*
M01AB*: acetic acid derivatives and analogues / *derivati dell'acido acetico e sostanze correlate*
M01AC*: oxicam / *oxicam*
M01AE*: propionic acid derivatives / *derivati dell'acido propionico*
M01AH*: coxib / *coxib*
NH: nursing home / *residenze assistenziali*
NSAIDs: non-steroidal anti-inflammatory drugs / *farmaci antinfiammatori non steroidei*

Table 1. Prevalence of potentially inappropriate prescribing before and after nursing home admission according to the selected STOPP criteria indicators.
Tabella 1. Prevalenza di prescrizioni potenzialmente inappropriate prima e dopo l'accesso in residenza sanitaria assistenziale secondo gli indicatori selezionati presenti nei criteri STOPP.

patients with chronic kidney disease were prescribed with NSAIDs.[15]

Even if indicator 5 was removed in the last update of STOPP criteria,[3] the proportion of patients affected by epilepsy and prescribed with phenothiazines after NH admission was higher than before NH admission, despite the use of these drugs is associated with a lowering seizure threshold. A possible explanation is the high use of phenothiazines in elderly patients concomitantly affected by both epilepsy and dementia,[16] even if their use should be always carefully evaluated in this subset particularly concerning safety issues (i.e., stroke and sudden death). Based on current evidence, second-generation neuroleptics are more likely to be appropriate for older patients with both dementia and epilepsy.[8,17]

The main strength of this study was the use of real-world data routinely collected for administrative and pharmacy management purposes, allowing to obtain information about patients' medical history, drugs dispensation, and hospital admission, then, to analyze the prevalence of PIP reducing the misclassification of patients at risk according to the specific indicator. Finally, using STOPP criteria rather than Beers criteria enable to be more sensitive in the PIP identification, especially given that STOPP criteria has been validated in the European elderly population, making their use more appropriate in the subset chosen for this study.[3]

The most important limitation is the lack of information on indication of use of medications, as it is not available in the administrative databases. Moreover, at the time of data collection, not all the Tuscan NHs were registered in the Regional administrative databases. Another limit may be represented by the lack of information on drugs not reimbursed by the Italian National Healthcare System. Although elderly residents in NH resort to the use of not reimbursed drugs less frequently, their use in this population cannot be completely excluded. Therefore, the results of this study may have been underestimated, particularly for NSAIDs. Patients were selected using hospital discharge records; therefore, non-hospitalized patients could not be selected. Additionally, this analysis should be applied with a study period longer than 2 years and more recent patient-level information. Finally, a cluster effect in the prescriptive behaviours that occur in the different NHs could not be completely excluded. Thus, in future, it would also be useful to explore the heterogeneity of the prevalence of PIP at NH level.

CONCLUSIONS

In conclusion, this study showed a decrease in the occurrence of PIP after NH admission for most of the considered STOPP indicators. The NH should be the clinical setting in which physicians, nurses, and other professionals interact to make right decisions about drug use avoiding PIP, especially in elderly. The reduction of PIP prevalence after NH admission may be related to raising awareness about the appropriateness of drug use. However, more efforts need to be made considering the persistence of PIP after NH admission. Further analysis may allow a comparison of this data with PIP prevalence in NHs in more recent years, describing the trend of this phenomenon over time.

Conflict of interest: none declared.

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Potentially inappropriate prescribing before and after nursing home admission: a retrospective observational study in a sample of Italian nursing homes

Potenziali prescrizioni inappropriate prima e dopo l'accesso nelle residenze sanitarie assistenziali: uno studio osservazionale retrospettivo su un campione di residenze sanitarie assistenziali italiane

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Supplementary Materials

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Table S1. STROBE Statement: checklist of items that should be included in reports of observational 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	1
		(*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	3-4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3-4
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	3-4
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	3-4
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	3-4
Bias	9	Describe any efforts to address potential sources of bias	NA
Study size	10	Explain how the study size was arrived at	NA
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	4
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	4
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	4
		(*e*) Describe any sensitivity analyses	NA

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	Item No.	Recommendation	Page No.
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	4
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	NA
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) *Cohort study*—Summarise follow-up time (eg, average and total amount)	4
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	4-5
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA
		Cross-sectional study—Report numbers of outcome events or summary measures	NA
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	NA
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done – e.g., analyses of subgroups and interactions, and sensitivity analyses	5
Discussion			
Key results	18	Summarise key results with reference to study objectives	5
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	6
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	5-6
Generalisability	21	Discuss the generalisability (external validity) of the study results	5-6
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	NA

* Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

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/; Epidemiology at: http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org