OBJECTIVES: The purpose of this project was to prepare and test culturally and linguistically appropriate versions of the SF-36v.2 in Crow and Salish. Prior translation efforts (e.g., IQOLA) have shown that cultural as well as linguistic considerations must be made when creating culturally-appropriate versions of the MOS SF-36 Health Status Survey (SF-36). The populations selected for this project were two Native American populations in Montana who are interested in preserving their native languages.

METHODS: Representatives of the Confederated Salish Kootenai Tribes (CSKT) expressed a preference for an English version of the SF-36; this was based on the need to preserve a pure form of the native language. Representatives of the Crow Tribe eventually decided to not participate in the study. In spring 2001, four hundred adult members of the CSKT were randomly selected to receive a mailed copy of the SF-36v.2 (English) along with a questionnaire (e.g., demographic, co-morbidity, and health care encounters), a cover letter, and a five-dollar incentive.

RESULTS: Response rate was 51% (205/400). Item-to-scale correlations ranged from −0.0166 (Pain) to +0.932 (Role-Emotional) with most in the 0.7 to 0.8 range. Scale-to-General Health Scale correlations were all positive, ranging from 0.2611 (Pain) to 0.5986 (Mental Health). The Pain Scale (Items 7 and 8) had the poorest item-to-scale and scale-to-General Health Scale correlations. The transformed norm-based z-scores for the CSKT population ranged from 38.1688 (Pain) to 48.1198 (Vitality).

CONCLUSIONS: While Native Americans may be interested in preserving and promoting the use of their native languages, they may not be interested in doing so in health surveys. The performance of all scales but the Pain Scale in the CSKT population appears to be good; however, further investigation into the Pain Scale results is needed. It is also important to recognize that other tribes may have different norms and response issues.

PREVENTABLE DRUG-RELATED MORBIDITY IN OLDER ADULTS IN NOVA SCOTIA, CANADA: DEVELOPMENT OF QUALITY INDICATORS

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The role of quality measurement of medication use is becoming more critical as consumers, employers and others demand increased accountability and transparency from the delivery of health care. At this time, however, there are no explicit quality indicators of preventable drug-related morbidity (PDRM) that could be used by clinicians and/or a health care organization.

OBJECTIVES: To create consensus-approved clinical indicators of PDRM in older adults applicable to the Canadian health care system.

METHODS: A written survey was constructed, listing the clinical outcome and pattern of care related to a number of possible PDRMs in older adults. Using the Delphi technique, two independent six-member expert panels (geriatricians, clinical pharmacologists) in Nova Scotia, Canada were asked to judge whether the outcome in each situation was foreseeable and recognizable, and whether causality was identifiable and controllable. The panel could also suggest additional PDRMs. Subsequently, a focus group of 12 general practitioners (GPs) evaluated these PDRM indicators. The inclusion of this third panel provided a triangulation of expert opinion across three practice areas.

RESULTS: The two expert panels proposed 58 indicators of PDRMs in older adults after two rounds of the Delphi technique. The GPs agreed with 52 (90%) of these PDRM indicators.

CONCLUSIONS: This study showed that consensus on quality indicators of PDRM can be reached among experts. These indicators could be used by a health care organization to proactively identify patients at risk for a PDRM and to improve the quality, safety and appropriateness of medication use. Additionally, the indicators form an important bridge between processes and outcomes of care and could be used in conjunction with existing medication use quality indicators. Subsequent phases of this study will involve pharmacist validation of these PDRMs, and identification (through an integrated medical database of older Nova Scotians) of patients who experienced PDRMs.

CONTENT ANALYSIS OF QUALITY OF LIFE AND PHARMACOECONOMIC MESSAGES IN PHARMACEUTICAL PRODUCT ADVERTISEMENTS

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Medical journal advertisements have been evaluated for pharmacoeconomic and quality of life (QoL) content, however no studies have compared advertisements from general health care (General) and managed care (MC) journals.

OBJECTIVES: The specific objectives of this study were to: 1) determine the number of pharmacoeconomic and QoL messages encountered in General and MC journals; and 2) evaluate the frequency of advertisements with respect to the type and content of pharmacoeconomic or QoL messages.

METHODS: The study was a review of all advertisements in six journals appearing from July 1999–June 2001. Journals were divided into two categories: General and MC. Three independent reviewers evaluated the content of each advertisement, and designated advertisements as those containing QoL, implicit or explicit, and/or pharmacoeconomic messages. Advertisements were also evaluated based on their use of supporting evidence for these messages. Advertisements in General and MC
journals were compared using descriptive and comparative chi-squared statistics.

RESULTS: 4,036 advertisements were identified from all issues in three General and three MC journals with 194 unique advertisements evaluated for potential outcomes messages. General and MC journals had QoL messages included in 36.0% and 41.7% of advertisements (p < 0.005) and pharmacoeconomic messages in 7.3% and 9.0% of advertisements (p = 0.08), respectively. MC journals had more advertisements detailing pharmaceutical expenditure savings (p = 0.01) and listing specific costs (p = 0.001). Trends for increased implicit QoL (p = 0.07) and QoL references (p = 0.08) in advertisements were found in MC journals.

CONCLUSIONS: Leading journals contain large numbers of QoL advertisements, with MC having significantly more than General journals. MC journals are also more specific as to the details of the cost data, however very few advertisements contain these messages. Increased detail in both QoL and pharmacoeconomic advertisements will help improve communication of this timely data.

CARDIOVASCULAR DISEASES/DISORDERS—
Clinical Outcomes Presentations

EFFICACY OF AMLODIPINE IN REDUCING SYSTOLIC BLOOD PRESSURE: A SYSTEMATIC REVIEW OF THE LITERATURE
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OBJECTIVE: To perform a systematic review of the literature pertaining to the efficacy of amlodipine monotherapy in reducing systolic blood pressure (SBP) in a variety of patient subgroups. The sixth report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VI) recommends diuretics or long-acting dihydropyridine calcium channel blockers (CCBs) for the treatment of isolated systolic hypertension (ISH). Amlodipine is the most commonly prescribed CCB worldwide; therefore, a systematic review was performed to capture the impact of amlodipine monotherapy on SBP.

METHODS: Following a protocol that had been developed a priori, published literature in five languages was searched from 1980 to 2001, using three electronic databases and manual bibliography checks of recent review articles and all accepted studies. Randomized controlled trials with at least 10 patients, one treatment arm of amlodipine monotherapy, minimum treatment duration of 8 weeks, reporting baseline and endpoint BP, and presence of baseline hypertension (defined as SBP ≥140 mm Hg, diastolic blood pressure (DBP) ≥90 mm Hg, or both) were accepted for this systematic review.

RESULTS: A total of 696 citations were reviewed, of which 85 met all inclusion criteria. Comparable treatment arms were pooled, and weighted means of efficacy results were calculated. In the amlodipine monotherapy arms, representing over 5,000 patients treated with the drug, amlodipine reduced SBP by an average of 17.5 mmHg from baseline (an estimated 13.3 mmHg more than placebo). The effect of amlodipine in reducing SBP was even more marked in elderly patients (24.1 mmHg mean reduction), black patients (23.9 mmHg mean reduction), and patients with ISH (25.9 mmHg mean reduction), although the number of studies investigating these special populations was small.

CONCLUSION: Amlodipine is effective for reducing SBP. Long-term trials are needed to correlate SBP reduction with clinical outcomes.

ADVERSE EVENTS IN CABG TRIALS: A SYSTEMATIC REVIEW AND ANALYSIS
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OBJECTIVES: To quantify the incidence of major adverse events (AE) occurring in hospital or within 30 days after surgery in patients undergoing coronary artery bypass grafting (CABG), and identify risk factors for these AEs.

METHODS: A systematic review and analysis of studies published in English since 1990. Studies of isolated standard CABG reporting post-operative incidence of myocardial infarction (MI), stroke, GI bleeding, renal failure, or death in hospital or within 30 days, were eligible. The incidence of these events was calculated overall, and for selected patient groups defined by: all elective CABG vs. mixed (elective and urgent/emergency CABG); mean ejection fraction (EF) <50% vs. >50%; mean age <60 years vs. >60 years; primary CABG only vs. some patients with reoperations; RCTs vs. cohort studies; single center vs. multicenter studies. Odds ratios of selected AEs were computed according to group risk factors.

RESULTS: 176 studies (205,717 patients) met all inclusion criteria. The average incidence of major AEs occurring in-hospital was: death —1.7% (range 0%–6.6%), non-fatal MI—2.4% (range 0%–13.9%), non-fatal stroke—1.3% (range 0%–3.2%), GI bleeding—1.5% (range 0.7%–2.7%), and renal failure requiring dialysis—0.8% (range 0%–6.2%). Thirty-day mortality was 2.1% (range 0%–7.7%). Subset analyses revealed interesting differences in overall mortality and MI incidence by groups with all elective vs. mixed CABG, by study design, mean age, primary CABG vs. some patients with re-operation, and by number of study sites. Meta-analyses of odds ratios suggest that old age (>70 years); female gender; low EF; history of stroke, MI, or heart surgery;