

anti-hypertensive drug class was assessed in the calendar year (CY) 2000. The time to the incidence of dementia was assessed from CY2001 to CY2002. A Multivariable Cox regression model adjusted for sociodemographic factors, comorbidities, comedications and other factors was constructed to estimate the adjusted relative risk of dementia associated with use of AHT drug classes. The analysis was stratified for patients with and without hypertension. **RESULTS:** A total 377,838 patients were included in the final analysis. The adjusted Hazard Ratios [HRs, (95% CI)] for risk of dementia with different classes was: Angiotensin receptor blockers (ARB) 0.76 (0.70–0.83), Angiotensin converting enzyme inhibitors (ACEI) 0.89 (0.85–0.93), CCB 0.93 (0.89–0.97), Diuretics 0.86 (0.83–0.90), Alpha blockers 1.05(1.00–1.09) and Beta-Blockers 0.96 (0.92–1.00). Only ACEI and ARB were significant in a stratified analysis of patients with HT (ACEI 0.89, 0.85–0.93; ARB 0.78, 0.71–0.85) and patients without HT (ACEI 0.81, 0.69–0.94; ARB 0.55 (0.34–0.88)). **CONCLUSIONS:** Drugs acting on the Renin-Angiotensin system (RAS) may be protective for dementia irrespective of the status of hypertension. More studies are required to explore this association further.

DB3

DIRECT AND INDIRECT COSTS ASSOCIATED WITH DIABETES PATIENTS WITH AND WITHOUT MACROVASCULAR COMORBIDITIES IN THE UNITED STATES

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OBJECTIVES: Macrovascular disease remains a common and costly comorbidity in patients with diabetes. The purpose of this study was to examine the marginal impact of macrovascular comorbidities on direct and indirect costs associated with patients with diabetes in the United States. **METHODS:** Using the pooled Medical Expenditure Panel Survey (MEPS) 2003 and 2005 data, a nationally representative adult sample (age >= 18) was included in the study. Direct cost was measured by the total health care expenditure. Indirect cost was calculated from the lost productivity from missed work days and additional bed days due to illness/injury based on the 2005 average national hourly wage. The direct costs of both 2003 and 2005 data were adjusted to 2005 dollars. Given the heavily right-skewed distribution of the cost data, GLM with log-link function and gamma variance was used to identify the relationship between macrovascular conditions and costs after controlling for age, sex, race, ethnicity, education, income, smoking status, health insurance, and number of other comorbid categories. Negative binomial models were applied to analyze the outcomes of missed work days and bed days. All statistics were adjusted using the proper sampling weight from the MEPS. **RESULTS:** The average annual health care expense for patients with diabetes was \$10,909. The average annual missed work days and additional bed days due to illness/injury for patients with diabetes were 6.3 and 14.8, respectively, equivalent to \$2366 in total. Compared to diabetes patients without macrovascular comorbidities (N = 3132), those with macrovascular comorbidities (N = 762) had statistically significant higher annual health care expenses (\$3587, p < 0.001), more missed work days (4.05, p < 0.01) and more bed days (7.15, p < 0.001). The marginal lost productivity cost was \$1257 annually. **CONCLUSIONS:** Macrovascular comorbidities in patients with diabetes result in increased direct and indirect costs.

DB4

COST OF DIABETIC-RELATED COMPLICATIONS AND CARDIOVASCULAR EVENTS BY TYPE OF EVENT AND SETTING ANNUALLY FOR THE FIRST THREE YEARS FOLLOWING ITS ONSET

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OBJECTIVES: This study evaluates using Tobit regressions the costs specific to each type of complication following its onset in annual increments for three years by setting (inpatient and outpatient). **METHODS:** We use a U.S. managed care database to identify newly diagnosed type 2 diabetics and then identify the initial onset of manifestations of diabetic related complications. Detailed ICD-9 codes associated with each type of complication were used to define dichotomous variables as well as a time to event variable, one for each selected type of complication. Outpatient and inpatient costs were accrued for one, two and three year periods. Because of the number of zero costs (i.e., not everyone consumes resources such as hospitalization annually), Tobit regressions were used, a combination of a probit probability model and a linear regression to resolve the disproportionality in resource utilization. Parameter estimates from a Tobit are not directly interpretable as those from a linear regression and require transformation to obtain the predicted cost values. **RESULTS:** A total of 351,900 type 2 diabetics were used in the analyses; 663 patients consumed inpatient services compared to 226,972 patients consuming outpatient services in year one related to a manifestation of a diabetic related complication. For those who encountered inpatient services, ischemic heart disease (\$43,269), congestive heart failure (\$43,870), ketoacidosis (\$29,588) and renal manifestations (\$24,995) were the most costly. Outpatient costs for these complications were significantly less, \$682, \$781, \$1,031, and \$1,267, respectively. Following the onset of these complications additional costs continued to accrue in year 2, \$50,158, \$51,669, \$35,080 and \$28,823, albeit at a declining rate. The total first year cost across all types of complications was \$2,827 per person (a 0.00993 first year event rate). **CONCLUSIONS:** The cost of diabetic-related complications is considerable even in the first year of newly diagnosed type 2 patients.

PODIUM SESSION III: HEALTH TECHNOLOGY ASSESSMENT

HT1

ANALYSIS OF FACTORS ASSOCIATED WITH REIMBURSEMENT DECISION MAKING IN HEALTH TECHNOLOGY ASSESSMENT (HTA)

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OBJECTIVES: Health technology assessment is used to inform reimbursement decisions for pharmaceuticals globally. The national HTA agencies of the developed world have broadly similar methods and use common factors when evaluating technologies but sometimes come to different decisions. The aim of this study was to investigate the context level and product-related level factors affecting reimbursement decisions between countries. **METHODS:** A systematic search was conducted to obtain the documentation for reimbursement decisions on cancer and cardiovascular medicines. Where insufficient information was published, or reports were not available in English, decisions were excluded. The analysis was conducted using multinomial logistic regressions and the independent variable included three types of decision: recommended, recommended for restricted use and not recommended. **RESULTS:** Detailed information was obtained on 194 decisions from Australia, Belgium, Canada, UK, France, and Sweden. The pooled analysis showed that 27% of medicines were recommended, 41% were recommended for restricted use and 32% were not recommended. The results demonstrated that several factors were important in producing the different types of decision. These included the number of RCTs, publication date, sensitivity analysis, budget impact, type of medicine and public interest. A sub-analysis for decisions in England showed that the cost per QALY value was statistically significant. **CONCLUSIONS:** The results may in part be explained by the different approaches between countries to conducting economic analysis, differences in cost-effectiveness thresholds and variation in the weight given to economic evidence. Further variation may be explained by factors relating to the country context such as the norms, culture and policy objectives which influence the methods and importance of different product level factors included in the HTA. The next stage of the research will investigate these factors directly.

HT2

HEALTH TECHNOLOGY ASSESSMENT – A COMPREHENSIVE FRAMEWORK FOR EVIDENCE-BASED RECOMMENDATIONS IN ONTARIO

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OBJECTIVES: This work describes the development of a framework for health technology decisions for Ontario Health Technology Advisory Committee (OHTAC) in Ontario, Canada. The focus of the work is on the development of an explicit framework for the recommendation of adoption of new health technologies. **METHODS:** OHTAC convened a "Decision Determinants Sub-Committee" in January 2007 which undertook a systematic literature review and conducted key informant interviews to develop an explicit decision making framework. The purpose of the literature review and key informant interviews was to examine methods and models relevant in our setting. The main research questions were the following: a) what criteria are used to make health technology recommendations?; b) what methods are used to evaluate health technologies using these criteria (e.g., assigned weights, ranking, rating)?; and c) what methodology is used to synthesize these criteria (e.g., process/rules/frameworks). **RESULTS:** Given the literature review and views provided by key informants, the "Decision Determinants Sub-Committee" offered recommendations about decision criteria, and the process by which decisions are made. Decision criteria include 1) overall clinical benefit; 2) consistency with societal and ethical values; 3) value for money; and 4) feasibility of adoption into the health system. The sub-committee drew on several key ideas: evidence based medicine to reflect the primacy of scientific evidence, cost-effectiveness analysis to reflect the importance of using society's resources wisely, and "Accountability for Reasonableness" to describe the elements of a fair decision-making process, and a deliberative process to describe how separate attributes of health technology ought to be evaluated and weighed. **CONCLUSIONS:** This methodology is currently being pilot tested in a live environment: OHTAC. It will be evaluated and revised according to its feasibility, acceptability and perceived usefulness. The transparency of the process should enable one to have a clear understanding of how OHTAC arrives at its recommendations regarding specific technologies.

HT3

A FRAMEWORK FOR DERIVING A MINIMALLY ACCEPTABLE TARGET CLINICAL PROFILE AND A MAXIMUM VALUE-BASED PRICE FOR DRUGS IN DEVELOPMENT TO MEET HEALTH TECHNOLOGY ASSESSMENT REQUIREMENTS

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OBJECTIVE: Advancement of innovative drugs into commercial development is increasingly subjected to rigorous internal reviews by manufacturers for minimal