behaviors, medication adherence, clinical factors, and quality of care. Cross-product terms were specified to evaluate differential effectiveness for subjects with differing clinical conditions including renal insufficiency based on GFR, obesity, longer duration of diabetes, and older age. RESULTS: A1C was lowered by 1.14 points (95% CI: 1.11–1.17) within one year after initiating new therapy, but only 30.2% (95% CI: 29.2–31.1%) achieved target (A1C < 7%). Mean A1C was 9.01 (8.98–9.04) prior to initiation and 7.87 (7.85–7.90) at 3–12 months after baseline. While baseline disease severity differed across initiators of each therapeutic class, there were no statistically significant differences in glycemic lowering across classes, or across clinical conditions.

CONCLUSIONS: Therapy initiation resulted in an impressive population-level benefit, similar in magnitude to that reported in randomized trials. Nonetheless, most patients failed to achieve glycemic targets after initiation possibly because providers had delayed intensification or patients failed to fill earlier prescriptions until they had advanced to very poor control. While no population-level differences in response by therapy were detected, in any one patient, differential response by class can not be excluded. The substantial glycemic response following initiation suggests that providers are probably choosing therapies for intensification wisely, but that earlier addition of a new agent may be beneficial.

SELF MONITORING OF BLOOD GLUCOSE IN PATIENTS WITH TYPE 2 DIABETES: COST UTILITY ANALYSIS IN A UNITED STATES THIRD-PARTY PAYER SETTING
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OBJECTIVES: Previous studies have shown that for patients with type 2 diabetes, self-monitoring of blood glucose (SMBG) can improve glycemic control (with HbA1c improvements of 0.3–0.6%), depending on treatment received). This in turn, can reduce risks of disease complications. Because monitoring supplies can have high acquisition costs, country-specific evaluations of SMBG cost-effectiveness are needed. The aim of this analysis was to estimate, within a US setting, the cost-effectiveness of using SMBG. METHODS: A validated, published model for type 2 diabetes (The CORE Diabetes Model) was used to project improvements in quality-adjusted life expectancy (QALE), long-term costs and cost-effectiveness of SMBG. A series of Markov models simulated the progression of diabetes-related complications (cardiovascular, neuropathy, renal and eye disease). Transition probabilities and HbA1c-dependent adjustments came from major epidemiological studies. Costs of complications were derived from published sources. From a US third party payer perspective, direct costs of diabetes complications and of SMBG were projected over patient lifetimes. Outcomes were discounted at 3% annually. RESULTS: Depending on type of treatment (diet/exercise, oral medications, or insulin), greater glycemic control with SMBG improved (discounted) QALE by 0.13 to 0.32 QALYs and increased total costs by $2089 to $4661 per patient. The resulting incremental cost-effectiveness ratios ranged from $13,848 to $35,880 per QALY gained, and were well within current willingness-to-pay limits. SMBG was most cost-effective in patients being treated with oral antidiabetic medication, and those being treated with insulin therapy. CONCLUSIONS: Within the three treatment regimens examined, the addition of SMBG was associated with increased glycemic control and with improved clinical and economic long-term outcomes. The incremental cost-effectiveness ratios were of magnitudes typically considered to indicate good value for money. Additional comparative studies are needed to further assess utilities and other standard outcomes associated with SMBG in patients with type 2 diabetes.

ECONOMIC STUDIES I

COST-UTILITY ANALYSES OF NEW MEDICAL TECHNOLOGIES: OFTEN COST-EFFECTIVE, SOMETIMES COST-INEFFICIENT, DOMINANT, OR DOMINATED, BUT ALMOST NEVER "DECREMENTALLY" COST-EFFECTIVE
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OBJECTIVES: Technological innovations may be cost-increasing and quality-improving (CIQI), cost-saving and quality-improving (dominant), cost-increasing and quality-decreasing (dominated), or cost-saving and quality-decreasing (CSQD). We endeavored to determine how cost-utility analyses of new medical technologies are distributed across these categories. METHODS: We systematically searched computerized databases including MEDLINE, HealthSTAR, CancerLit, Current Contents and EconLit to identify cost-utility analyses published in 2002 to 2003. Trained auditors summarized each study using standardized forms. All costs were converted to 2002 US dollars. RESULTS: We identified 640 separate published cost utility analyses. These papers compared 657 interventions against a standard. Of analyzed interventions, 79.0% (519) were CIQI, 13.5% (89) were dominant, 6.7% (44) were dominated, but only 0.8% (5) were CSQD. Among CIQI interventions, 64.6% (335) had a cost-effectiveness ratio (CER) below $50,000 per QALY and 79.0% (410) had a CER below $100,000 per QALY. Among CSQD interventions, 60% (3) had a CER below $50,000 per QALY and 2 had a CER above $100,000 per QALY. CONCLUSIONS: Most published cost-utility analyses are performed on CIQI technologies, and most of these have a CER below conventionally accepted thresholds. Cost-utility analyses of CSQD technologies are extremely rare.

DIRECT MEDICAL COSTS OF SOLID ORGAN TRANSPLANT IN BRITISH COLUMBIA, CANADA
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OBJECTIVE: Solid organ transplants are among the most resource-intensive of treatments. There exists only limited knowledge of the current costs of solid organ transplants in Canada because existing studies were derived from single centres, included different resource categories, covered different time periods, and used different cost methodologies. The purpose study was to derive population-based estimates of the direct medical costs of kidney, liver, lung and heart transplants in British Columbia (BC), Canada, from 1995 to 2003. METHODS: Province wide resource utilization data were extracted from the BC Transplant Society. This population-based registry includes records of all persons undergoing solid organ transplantation in BC. Unit cost data were obtained from publicly available sources. Health resources categories included inpatient hospital stays, outpatient visits, physician fees, laboratory and diagnostic tests and immunosuppressant medications. Mean (standard deviation (SD)) costs were derived separately for the transplant pro-
cEDURE and for each of the two years post-transplant and reported in 2003 Canadian dollars. RESULTS: The mean costs over all periods was $7706 for 876 persons undergoing kidney transplant, $28,737 for 257 persons undergoing liver transplant, $43,719 for 67 persons undergoing lung transplant and $31,152 for 133 persons undergoing heart transplant. The largest component for all organs was the cost of the procedure and the initial hospitalization. The mean (SD) costs in the first and second post-discharge years were, respectively, $21,552 (326) and $11,103 (1260) for kidney, $21,146 (1273) and $8090 (535) for liver, $27,593 (4801) and $11,426 (1144) for lung and $22,588 (1044) and $9777 (520) for heart. Immunosuppressant medications comprised the largest single cost component during follow-up. CONCLUSION: There was six-fold variation in direct medical costs between the least and most expensive solid organ transplant procedures. The variation in costs diminished between programs over the first and second years post-transplant.

**PROCESS OPTIMIZATION IN A 10-BED INTENSIVE CARE UNIT (ICU) IN GERMANY: IMPACT ON CASE-RELATED TREATMENT COSTS**

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OBJECTIVES: To estimate the impact of the following Process optimization (PO) measures implemented during 2002 on case-related treatment costs (CRTC) in the ICU of a midsize German hospital, from the hospital perspective: optimization of diagnostic procedures, standardization of medical devices, improved management of treatment courses, expansion of renal replacement therapies, and replacement of fentanyl/midazolam (FM) by remifentanil/propofol (RP) throughout for analgosedation within a standardized concept for mechanical ventilation.

METHODS: A retrospective cost-consequence analysis was performed comparing 2 intervals: years 2000–2001 before and years 2003–2004 after PO. Data on baseline characteristics, treatment, outcomes, and resource utilization (staff, laboratory, medical need) of the ICU cases came from the routine documentation of the ICU. Resources were valued in 2004 internal hospital prices. Differences in CRTC and components between the intervals were regarded significant with a p value <0.05. RESULTS: There were no significant differences in baseline characteristics, distribution of intensive treatment to monitoring, ventilation days, and case-related mortality between the totals of 1704 and 2044 cases treated before and after PO, respectively. CRTC, however, significantly dropped by 25% from €2435 before to €1815 after PO, comprising staff expenses (from €1636 to €1238), laboratory cost (from €60 to €41), and cost for medical need (from €718 to €536). The per-case cost for medical need significantly decreased although 2 of its 14 cost categories showed considerable increases: cost for renal replacement therapies were 2.9-fold after PO due to expansion of this kind of treatment and cost for analgosedation were 2.1-fold after PO due to using RP instead of FM. CONCLUSIONS: The whole PO improved the efficiency as indicated by significantly decreased CRTC at similar case-related mortality. Using RP throughout for analgosedation of mechanically ventilated patients as an integral part of a comprehensive PO strategy can result in savings of CRTC in the ICU.

**SYSTEMATIC REVIEW OF BUDGET Impact ANALYSES**

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OBJECTIVES: Although only 7 pharmacoeconomic and 6 submission guidelines require partial or total budget impact analyses (BIA), affordability is becoming a key issue to decision-makers. Our aim was to review the published BIAs according to different quality assessment criteria. METHODS: PubMed and EMBASE were searched for articles with the search terms “budget impact” or “budget analysis” limited to English language. Relevant articles were abstracted by aim, funding, technology and various issues concerning the analyses. RESULTS: 16 studies were found between 2001 and 2006, the majority prepared for pharmaceuticals, and from the US; however, 50% had BIA only as complementary calculation to economic evaluations. In the US, due the dominance of private health insurance, and in France due to the submission requirements, all studies had BIA as their main aim. Industry funding was stated for 63%; however, industry affiliation was present for a further 13%. In accordance with the aim of assisting NHS systems and insurance companies determine affordability, the payer perspective was chosen in all of the studies, complemented in a few cases by patient or societal perspective. Direct medical costs (63%) or only drug costs (19%) were assessed mostly for one year (44%). Epidemiological data or rate of adoption was mainly based on literature and assumptions. Results were reported by resource type in only 6 (38%) studies, even though this would help to realize a re-deployment of resources. The majority (56%) were either cost-saving or had cost-saving scenarios. A sensitivity analysis was done in only half of the studies for BIAs and in a further 25% for economic evaluation only. CONCLUSIONS: Although affordability is major issue in health care finance, BIAs are still rare and frequently do not seem to generate independent analyses. The quality of many studies also fails to reach desired attributes.

**GI DISORDERS**

**COST OF FUNCTIONAL DYSPEPSIA—RESULTS FROM A LARGE US EMPLOYER DATABASE**

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OBJECTIVES: Data from Sweden (Nyren 1992) shows the annual frequency of consultations for functional dyspepsia (FD) to be estimated at 47/1000 population with a costs estimated at SUS113,630/1000 population (1991 dollars). No published data exists for US based employers on the costs associated with FD. To assess the economic burden of FD associated with medical costs and work loss from an employer perspective. METHODS: A review was conducted using a person-centric database containing costs from multiple large geographically diverse US based employers between 2001–2004. Claims data included pharmacy, medical, short- and long-term disability (STD, LTD), sick leave (SL), and productivity measurements. Comparisons were made between FD employees (ICD-9 code of 536.8) and employees without FD. Data were compared for a 12-month period beginning 3 months prior to the first diagnosis of FD (the index date). The average index date from the FD cohort was assigned for the control group. Multiple regression and Markov modeling techniques along with Charlson Co-Morbidity Index to adjust for