EM3

RESPONSE BIAS AMONG LIKELY CLINICAL TRIAL PARTICIPANTS

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OBJECTIVE: To understand the demographic, attitudinal, behavioral, and clinical characteristics of people who are likely to participate in clinical trials. **METHODS:** Analyses were based on a 12-page questionnaire mailed to U.S. adults in 2000. A total of 21,986 responses were received. Respondents were nationally representative based on gender, age, race, and geographic region; results were subsequently weighted and projected to the U.S. population. Participants were asked if they had ever participated in a clinical trial and whether they would ever consider participating in one. **RESULTS:** Among those who never participated in a clinical trial, 33% said they would strongly consider participating in the future. This group differed in some dramatic ways from the 26% who said they would definitely not consider participating in a clinical trial. For example, those who would participate were more likely to be female (55% v. 49%), younger (43 v. 47 years), and white (77% v. 70%). Behaviorally, likely participants were more likely to drink alcohol (64% v. 55%), smoke (27% v. 22%), visit physicians (4.0 v. 3.6 visits in six months), and use the internet for health care information (13% v. 6%). Attitudinally, those willing to participate were more likely to harbor alternative health care attitudes (e.g., "would try acupuncture" 38% v. 17%) and less likely to be satisfied with their current medical care (39% v. 47%). Clinically, they were more likely to be diagnosed with a range of comorbid medical conditions such as depression (15% v. 6%), migraines (16% v. 8%), and nasal allergies (32% v. 21%). **CONCLUSION:** People who are likely to participate in clinical trials look, think, and behave differently than those who are not likely to participate. Trail design and analysis should consider these differences and their possible impact on clinical, economic, and humanistic outcomes.

EM4

CAN UNIT COSTS BE COMPARED ACROSS WESTERN EUROPEAN COUNTRIES?

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OBJECTIVE: It is well documented that resource consumption and costs vary across settings. Unit costs can also vary. Using consistent cost-finding methods across and within five Western European (WE) countries unit costs of cardiovascular procedures were compared to examine the degree and impact of variation. **METHODS:** Unit cost data were collected from fee schedules, national averages and selected individual institutions. A bottom-up costing approach was used in hospitals based upon a definition of resources consumed for procedures. Hospital daily rates were calculated from an allocation of overhead accounts and a basic package of services such as nursing, housekeeping, dietary and pharmacy services. Costs were obtained in the local currency and converted directly to Euros. **RESULTS:** Unit cost variation was observed within and across countries. UK costs for percutaneous transluminal coronary angioplasty (PTCA) in 13 centers ranged between 1380 and 2700 Euros, 0.75–1.5 times the median. Inter-country cost variation for the same procedure ranged between 1850–4000 Euros, 0.60–1.3 times the median. Daily hospital general ward rates vary inter-country between 0.8 and 1.6 times the median, comparable to within country variation. Physician ambulatory visit costs from fee schedules that may not reflect actual costs were standard within country but varied across countries (0.5–1.2 times the median of 18 Euros). When applied to a consistent set of resources, differences in costs resulted in widely varying cost-effectiveness (CE) ratios by country. **CONCLUSIONS:** Obtaining comparable unit costs within countries is difficult. Center-specific costing is most reliable, but expensive and must be representative for submissions to national level health authorities. With standardized costing methods, the differences observed here cannot be explained by differences in accounting. Extreme care must be taken when transferring the results of CE analyses between centers, especially between countries.

MEDICAL DEVICE & DIAGNOSTICS

MD1

COST-EFFECTIVENESS OF AIRLINE DEFIBRILLATORS: IS PEACE OF MIND MORE IMPORTANT THAN SAVING LIVES?

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OBJECTIVES: Airline passengers are particularly vulnerable to the effects of cardiac arrest due to a lack of access to emergency medical services. To offset this isolation, airlines are installing automated external defibrillators (AEDs) on aircraft. Our objective was to measure the cost-effectiveness of airline AED programs and estimate their value to the flying public. **METHODS:** A decision analytic model was constructed to estimate the clinical and economic effects of airline AEDs. Inputs were obtained from published data and the FAA. Utility estimates were derived from cardiac arrest survivors. Sensitivity analyses evaluated changes in AED cost and probability of cardiac arrest. Since AEDs may provide utility gains through "peace of mind" for passengers not experiencing a medical event, the impact of this added passenger confidence was also evaluated. **RESULTS:** AEDs on commercial aircraft cost an incremental $5.16 per flight. AED deployment resulted in an estimated ad-

ditional $162,000 per QALY gained (16 quality-adjusted minutes per flight). Sensitivity analysis of event probabilities and cost inputs did not substantially change the results. However, the cost-effectiveness of AEDs was significantly enhanced by the inclusion of utility gain experienced by passengers from increased peace of mind. While the magnitude of this benefit is unknown, an incremental increase of .003 in utility over the flight duration would reduce the incremental cost-effectiveness of AEDs to less than $50,000 per QALY gained. **CONCLUSIONS:** Our model estimated that when the benefits of on-board AEDs are limited to patients experiencing medical events, the incremental cost-effectiveness is inferior to most recommended medical interventions. However, if passengers gain utility from knowing an AED is on the aircraft, then these incremental expenditures may be justified. Utility gains from "peace of mind" may have significant implications in determining the value of health care interventions. Further research should be conducted into this potentially important area.

MD2

ANALYSIS OF THE IMPACT OF ASSISTIVE LIVING DEVICES ON SELF-ASSESSED HEALTH STATUS RATING

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OBJECTIVE: Persons with limitations in Activities of Daily Living (ADLs) generally report a greater sense of independence when they have the use of assistive devices. Insurance companies have traditionally been reluctant to cover the cost of such devices, considering them to be non-essential equipment. Although the economic cost savings associated with a decrease in the need for external caregivers and institutionalization are calculable, the psychological benefits arising from this greater degree of independence seen in patients who use assistive devices tends to be overlooked. Therefore the main objective of this project was to determine the impact of assistive living devices on patients self-rated health status. **METHOD:** Medical Expenditure Panel Survey (MEPS) Household Component file 1998 P2R3/P3R1 was utilized for this project. The initial pool of 25,000 cases was narrowed using the inclusion criteria whereby all subjects must be 65 years or older, and have coded that they possessed one or more physical disabilities or limitations. This led to a final sample size of 1,025. Information on demographics, socioeconomic status and level of disability was extracted from the database for these patients. Multiple regression analysis was conducted with self-rating of health status serving as the dependent variable. The primary independent variable of interest was use or non-use of assistive living devices. Secondary independent variables included: marital status, sex, age, race, educational level, physical disabilities and limitations, and social limitations. **RESULTS:** Use of assistive devices, race, age, some forms of physical limitations and levels of education were significant in this model ($p < 0.05$). Marital status and gender proved to be insignificant factors. **CONCLUSIONS:** Use of assistive devices does have an impact on the way in which individuals with limitations and disabilities view their health status and therefore may be important contributors to their overall quality of life.

MD3

THE DIAGNOSTIC ACCURACY OF 18FDG-PET IN PATIENTS WITH RECURRENT PAPILLARY OR FOLLICULAR THYROID CANCER: A SYSTEMATIC REVIEW

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OBJECTIVES. Positron Emission Tomography with 18F-fluorodeoxyglucose (FDG-PET) is a new nuclear imaging technique that can detect recurrent or metastatic thyroid carcinomas. We conducted a systematic review to determine the diagnostic accuracy of FDG-PET in patients with papillary and follicular thyroid carcinoma. **METHODS.** Two unblinded reviewers independently selected, extracted and assessed data from relevant literature. Included studies were prospective or retrospective with 10 human subjects or more that evaluated the accuracy of FDG-PET in follicular and papillary thyroid cancer. Reviews, case reports, editorials, letters, and comments were excluded. The methodological quality of the included studies was assessed by the criteria for diagnostic tests recommended by the Cochrane Methods Group on Screening and Diagnostic Tests. A qualitative analyse was conducted to assess the value of FDG-PET in thyroid carcinoma. The rating system consisted of four levels of scientific evidence (1 = best; 4 = worst). **RESULTS.** Two of the fourteen included studies were considered of level 3 evidence. The other twelve studies provided level 4 evidence. Most prevalent methodological flaws regarded validity of reference tests and blinding of test interpretation. The overall conclusion in these studies was that FDG-PET appeared beneficial in patients with elevated thyroglobulin levels and negative 131I WBS. **CONCLUSIONS.** In conclusion, although FDG-PET may solve clinical problems in selected patients suspected of recurrent thyroid cancer, the present evidence does not allow for implementation of a routine diagnostic algorithm. Future studies should be designed to avoid the limitations presented in this review.

MD4

INCLUSION OF INDIRECT COST IN ECONOMIC OUTCOMES ANALYSES OF MEDICAL DEVICES: HOW IMPORTANT IS IT?

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OBJECTIVE: To evaluate the impact of indirect cost (due to absence from work, disability, mortality) in economic evaluations comparing minimally invasive proce-