compliance for these days exceeded 90%. Evidence for back and forward filling of paper diary cards was observed. For the compliance-enhanced electronic diary, the actual compliance rate was 93%.

CONCLUSIONS: Data from paper-based diaries are of questionable validity, given that many of their entries are not completed as required by the protocol. Science-based electronic diaries can produce high rates of patient compliance in the field. Improved methods for data collection should encourage researchers in the pharmaceutical industry to aggressively evaluate electronic PRO (ePRO) data to help differentiate their products.

### POWER CALCULATIONS FOR WIDELY USED PATIENT-REPORTED OUTCOMES (PRO) MEASURES IN WOMEN’S HEALTH TRIALS

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OBJECTIVE: Increasingly, federal authorities are requesting power calculations for secondary endpoints in clinical trials, including patient reported outcomes (PRO). However, most PRO measures do not provide power calculations in their manuals; if provided, they are often based on mixed samples of males and females. It is well documented that female and male PRO scores often differ. Thus, when designing women’s health trials, it may be worthwhile to conduct power calculations using women’s PRO scores and standard deviations. This study presents the power and sample-size calculations for a variety of questionnaires used in women’s health studies.

METHODS: The Menopause Quality of Life questionnaire (MENQOL), Women’s Health Questionnaire (WHQ), Psychological General Well-Being Index (PGWB), and Short Form 36 and 12 (SF-36/SF-12) were assessed. Published information on scores and standard deviations in female populations were used to determine sample sizes needed to detect differences between two experimental groups, post-intervention.

RESULTS: Results varied by questionnaire, due in part to varying score ranges across questionnaires. For example, to achieve 90% power with a ten-point difference the following sample sizes per treatment arm were required: 158 women when using the MENQOL vasomotor score (range: 0–100); 47 women when using the WHQ total score (range: 0–102); 70 women when using the PGWB total score (range: 22–132); 24 and 21 women when using the SF-36 and SF-12 Physical Component Summary (no floor/ceiling).

CONCLUSION: When calculating sample sizes, it is necessary to keep in mind the questionnaire’s possible score range in order to ensure that the power calculation is based on a clinically meaningful difference between treatment groups. These results may be used to help calculate sample sizes needed to achieve sufficient power to detect statistically significant differences in women’s health trials for these widely used measures.
OBJECTIVES: Patients with type 2 diabetes are known to make increased use of health-care resources, but the impact of specific macro and microvascular complications on costs is unclear. Here we use regression based methods to estimate the immediate and long-term impact of six diabetes-related complications on hospital costs, using data from the UKPDS, a large (n = 5102) and long-term (median duration 10.3 years) clinical trial.

RESULTS: Data on the occurrence and precise timing of pre-defined diabetes-related complications, and on all hospitalisations with associated specialties, lengths of stay, and procedures, were collected routinely for all patients during the trial. Panel data regression analysis was used to estimate the immediate impact (i.e. in the year event occurred) and long-term impact (i.e. in each subsequent year) of the following six diabetes-related complications on hospital costs: fatal and non fatal myocardial infarction (n = 828); fatal and non-fatal stroke (n = 271); heart failure (n = 166); angina (n = 319); blindness in one eye (n = 166); amputation (n = 67). Hospital costs were calculated using national average specialty-specific costs per inpatient day, expressed in 1999 £s UK.

METHODS: All six diabetes-related complications had a statistically significant impact on hospital costs. In the year in which the complication occurred, diabetes-related complications were associated with increased hospital costs ranging from £995 for loss of sight in one eye to £5478 for an amputation. In subsequent years the annual costs ranging from £995 for loss of sight in one eye to £319 for a stroke. Regression analysis on a large and well-validated, patient-specific data set yields plausible empirically based estimates of the hospital cost consequences of diabetes-related complications. These will be of use to other economists and health service researchers, particularly those interested in assessing the costs of diabetes and the cost-effectiveness of interventions within a modeling framework.

CONCLUSIONS: Regression analysis on a large and well-validated, patient-specific data set yields plausible empirically based estimates of the hospital cost consequences of diabetes-related complications. These will be of use to other economists and health service researchers, particularly those interested in assessing the costs of diabetes and the cost-effectiveness of interventions within a modeling framework.

BOTTOM UP VERSUS TOP DOWN COST ESTIMATES FOR TYPE 2 DIABETES
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OBJECTIVES: To compare top down and bottom up cost estimates of direct health-care costs for diabetes type 2 in the Netherlands.

METHODS: For the top down cost estimates we used comprehensive Dutch national age and sex-specific cost of illness estimates for diabetes and diseases related to diabetes complications. Costs for diabetes type 2 were separated by age (age 35 and older) and by prevalence rates for types 1 and 2. The costs of complications were estimated using costs and prevalence rates for cardiovascular diseases, neuropathy, nephropathy and retinopathy, combined with relative risks for these complications in patients with diabetes type 2. The bottom up costs were estimated using a sample of 1371 type 2 diabetes patients for whom their GP reported the total medical consumption related to diabetes and its complications during the previous six months.

RESULTS: Total medical costs for diabetes type 2 in 1998 were Euro 567 mln according to the bottom up estimate versus Euro 519 mln for the top down estimate, or less than 10 % difference in cost. The costs for in hospital care, ambulatory care and equipment were very comparable. The cost of medication was higher according to the bottom up study. The bottom up study identified a larger amount of cardiovascular and lipid lowering drugs. Both costing methods show that complications, especially cardiovascular, are responsible for a substantial portion of total health-care costs.

CONCLUSIONS: For diabetes type 2 it was demonstrated that using comprehensive top down disease costs combined with sound epidemiological data on complications, can yield valid cost estimates that are quite comparable with bottom up cost estimates.

A DYNAMIC, THREE-PART MODEL FOR PREDICTING HOSPITAL COSTS IN TYPE 2 DIABETIC PATIENTS
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OBJECTIVE: To develop a model for predicting hospital costs in patients with diabetes mellitus.

METHODS: We have previously shown that, in comparison with standard cost models, better prediction can be achieved with a two-part model that independently predicts risk of hospitalization and cost of hospitalization. In this analysis we have developed a three-part model by adding mortality to the original two-part model, because patients who die do not necessarily incur hospital costs in the year of death. Furthermore we have extended the three-part model to an autoregression model. Age, gender, any hospitalization in the last year, log-hospital costs in the last year and log-mean costs over all previous years were included in the model. A Bayesian forecasting method was used to obtain a predictive distribution of costs in the next year.

RESULTS: We identified 5672 type 2 diabetic patients in the Tayside area and analyzed annual hospital costs between 1988 and 1995. The fitted three-part model showed that increasing age was associated with increasing mortality and with increasing costs per hospital episode. However, age was not associated with the risk of hospitalization. Cost of hospitalization in previous years was positively associated with risk of hospitalization (OR = 1.51/ln(mean costs), CI = 1.48, 1.53) and mortality (OR = 1.22/ln(mean costs), CI = 1.19,1.25). An example of Bayesian cost forecasting showed that for female patients aged 50 to 59, increasing hospital costs in the previous year increased the probability of having a high-cost hos-