CONCEPTUAL PAPERS & RESEARCH ON METHODS – Study Design

PMC75

ARE ONLINE MANAGED PHYSICIAN PANELS A VIABLE SOURCE FOR SCIENTIFIC RESEARCH INITIATIVES?

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OBJECTIVES: Use of online "managed physician panels" for outcomes research purpose is not yet common. This study aims to compare practice characteristics, prescribing patterns and attitudes between physicians in 'TNS online managed panels' and free-bound non-panel samples. **METHODS:** Physicians, especially Neurologists, were recruited from two sources in the United States for a Multiple Sclerosis (MS) research initiative: via online using TNS online managed panels (panelists), and via telephone (non-panelists). Practice characteristics (12-items), attitudes (76 items), treatment choices (8-items) and ratings of risk-factors (36-items) were measured in both cohorts using a standardized 45-minute-questionnaire; the results were analyzed to assess any statistical difference between the panelists and non-panelists across the measured domains. **RESULTS:** Survey results from Neurologists (167-panelists & 97-non-panelists) were assessed. Overall, the concordance rate between the cohort responses was 95% (126-out-of-132-items). In 1 (out-of-12; 8.3%) practice characteristic, namely, patient (pt) volume treated in a typical month, the cohorts differed (panelists-312pts/non-panelists-277pts). In 5 (out-of-76; 6.6%) attitudinal items (in 7-point likert-scales), the individual item-response-scores marginally differed: importance of considering patient lifestyle while selecting MS therapy (panelists-4.8/non-panelists-5.2), importance of brain lesions in measuring MS progression (panelists-5.1/non-panelists-5.4), patients experience more side-effects with interferons than with glatiramer-acetate (panelists-5.8/non-panelists-5.3), interferon therapies with more frequent dosing are more effective (panelists-4.5/non-panelists-4.1), and physician opinion on what is best for patient supercedes patient's personal preferences (panelists-4.2/non-panelists-3.8). There were no statistically significant differences observed between the cohorts in treatment choices (all 8-items) and ratings of risk factors (all 36-items). **CONCLUSIONS:** The high concordance rates observed in the study cohort characteristics, attitudes and treatment practices strengthens the argument that online managed physician panels are viable options for scientific research studies, as they provide robust, cost-effective, quick sample of physicians, in addition to the well-known relatively high response rate.

PMC76

PATIENT REGISTRIES—A LITERATURE REVIEW OF RECENTLY REPORTED REGISTRY BASED STUDIES

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Patient registries have been gaining increasing attention in recent years as health care providers, payers and regulators are requiring data that more accurately reflect clinical practice. However while the number of registry based studies is undoubtedly increasing, little is known about the range and characteristics of registries supporting these studies. A review of the published literature was performed to identify recently reported studies based on patient registries. The search which covered the period January 2008 to April 2009 retrieved 278 evaluable articles reporting data from disease (55%), exposure (42%) and pregnancy (3%) registries. The majority of studies based on disease registries were focused on cardiovascular disease (49%), oncology (12%), renal disease (10%), haematology (8%) and gastrointestinal disease (7%). Data from exposure registries reported on patients who had received a pharmaceutical product (47%), device (28%), undergone a surgical procedure (22%) or other intervention including radiotherapy (3%). Several registries have provided data able to support multiple publications for example the REACH registry. The most frequently performed assessments were evaluation of benefit (46%), risk (34%), treatment practice (31%) and burden of disease (23%). Local or nationally representative patient registries accounted for 83% of the total reviewed. This might be expected given that data is most frequently required in the context of national health care systems by different stakeholders. However, one new insight this study provides is the use of studies based on an international registry (17%) where design, implementation and management provide much bigger challenges. Further analysis is underway. This research has confirmed that patient registries are being used to provide evidence to inform health care decision making, improve disease management and advance knowledge on the benefits, risks and cost effectiveness of different interventions in clinical practice.

DIABETES/ENDOCRINE DISORDERS – Clinical Outcomes Studies

PDB1

A COMPARISON OF CLINICAL EFFICACY OF INSULIN GLARGINE ADDED TO ORAL ANTIDIABETIC DRUGS VS PREMIXED INSULINS ALONE IN THE TREATEMENT OF TYPE-2 DIABETES MELLITUS

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OBJECTIVES: This study compared efficacy and safety of insulin glargine (IGlar) when added to oral antidiabetic agents (OADs) with premixed human insulins alone in type-2 diabetes. **METHODS:** Comparison was based on randomized controlled trials (RCT) identified by means of systematic review, carried out according to the Cochrane Collaboration guidelines and Agency for Technology Assessment in Poland. The most important medical databases (EMBASE, MEDLINE and CENTRAL) were searched in October 2008. Two reviewers independently selected trials, assessed their quality and extracted data. Meta-analysis of head-to-head trials was performed to compare IGlar added to OADs with premixed insulins. **RESULTS:** Three RCTs (637 patients) directly comparing IGlar added to OADs with premixed human insulins were identified and included in the analysis. Greater reduction of glycated hemoglobin (HbA_{1c}) was found in glargine-treated patients than in patients using premixed insulins (WMD = −0.33% [−0.50; −0.16]). Proportion of patients achieving HbA_{1c} ≤7% was also higher in IGlar group although the difference was on the border of statistical significance (RR = 1.26 [1.00; 1.59]). Moreover statistically significant differences in favor of glargine were demonstrated in fasting plasma glucose level (WMD = −0.87 [−1.21; −0.53]). More subjects treated with glargine achieved target FPG level (RB = 2.11 [1.41; 3.17], NNT = 6.00 [3.97; 12.32]). No statistically significant differences were found in the percentage of patients experiencing hypoglycemic episodes(RR = 0.90 [0.78; 1.04]). Weight gain was observed in both groups with no statistically significant differences (MD = −0.70 kg [−1.48; 0.08]). **CONCLUSIONS:** IGlar combined with OAD is associated with better glycemic control than premixed human insulins alone. Risks of hypoglycemia and weight gain are comparable in both arms. Acknowledgements:

PDB2

REAL WORLD CLINICAL EFFECTIVENESS OF SITAGLIPTIN THERAPY FOR MANAGEMENT OF TYPE 2 DIABETES: A RETROSPECTIVE DATABASE ANALYSIS

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OBJECTIVES: Sitagliptin is a dipeptidyl peptidase-4 inhibitor used to treat adults with type-2 diabetes (T2D). This study examined patient characteristics and clinical effectiveness of sitagliptin in a managed care setting. **METHODS:** An administrative claims analysis was performed using data from the HealthCore Integrated Research database. Adults with a diagnosis of T2D, a new claim for sitagliptin (index medication) between October 1, 2006 and March 31, 2007, and ≥12 months pre- and post-index continuous eligibility were included (n = 3719). A subgroup analysis was performed for patients who had baseline (183 days pre-index—30 days post-index) and post-index (60–365 days) HbA1C (A1C) data to examine change in A1C after sitagliptin initiation. **RESULTS:** Mean (SD) age of patients initiating sitagliptin was 56.0 (±10.0) years and 61% were male. Common co-morbidities were hypertension (84%), dyslipidemia (83%), and other cardiovascular diseases (25%). At baseline the patients were receiving an average (SD) of 1.9 (±1.0) antidiabetic medications. Commonly used antidiabetic medications were metformin (58%), thiazolidinediones (41%), sulfonylureas (37%) and insulin (16%). While not an approved indication, there was a significant increase in the use of insulin therapy from 16% to 25% in the post index period (p < 0.0001). Fixed dose oral combination therapy also increased from 19% to 25% in the post-index period (p < 0.0001). Mean (SD) baseline A1C in the subgroup (n = 726) was 8.02% (±1.56) with an absolute reduction of 0.54% (±1.44), (p < 0.0001). Of 522 patients with a baseline A1C ≥ 7.0%, 178 (34.1%) achieved an A1C of <7.0%. **CONCLUSIONS:** Most of the patients initiating sitagliptin therapy were also using other antidiabetic medications at baseline. There was a significant increase in concomitant use of fixed dose combination and insulin therapy in 12 months following sitagliptin initiation. The mean reduction in A1C and the proportion of patients attaining A1C <7.0% were comparable to those observed in clinical trials.

PDB3

FORECASTING THE NUMBER OF DIABETIC PATIENS IN THE UNITED STATES IN 2050

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OBJECTIVES: Accounting for changing demography and diabetes prevalence rates, to project the number of people with diagnosed diabetes in US through 2050. **METHODS:** Our model proceeds in three steps using inverse probability weighting and raking.Created initial sampling weights, defined as the inverse of the probability of selection, plays a pivotal role in desing-based inference in yielding estimates that are designed unbiased and consistent. Last, by applying procedure, known as raking, we adjust our initial weights so that marginal total of adjusted weight on specified characteristics agrees with the corresponding totals for the population. **RESULTS:** The total number of people with diabetes will rise to almost 26 million in 2025. This is projected at 200% increase over the 2000 levels. Note that these projections imply steady increase in the overall prevalence of diabetes. The largest increases in the number of people with diabetes likely to occur in the older age. The number of women 75 years or greater of age with diabetes will increase almost 380% from 2000 levels. It is demographic changes that account for the largest share of the increase. Twenty percent of the overall projected growth will be due to population growth, 35% will be due to increase in prevalence rate and 45% will be due to changes in demographic compositions. **CONCLUSIONS:** Diabetes is already recognized as publich health problem of pandemic proportions. Our projection of diabetes burden in US indicate that the situation may be more alarming than previously recognized. Advances in primary prevention may help reduce the number of people with diabetes. The economic burden of diabetes is already staggering, and future increase in the number of people with the disease will increase the burden. Worldwide surveillance of diabetes is a necessary first step toward its prevention and control.