OBJECTIVE: To survey healthcare professional (HCP) recommendations and patient practices regarding blood glucose self-monitoring among type-2 diabetic (T2D) patients receiving pharmacotherapy and to investigate the potential impact of a new incretin mimetic therapy (IMT). METHODS: HCPs in the UK (N = 50) were interviewed using structured questionnaire methodology. The survey investigated recommended and actual frequencies of self-monitoring according to type of therapy (oral therapy alone [oral(s)], insulin ± oral therapy) and phase of treatment (initiation, steady state), and investigated self-monitoring recommendations for the IMT. Additionally, patients with T2D (N = 26) were questioned by structured telephone interview. RESULTS: The average frequency of self-monitoring recommended by HCPs was 3–4 times higher for patients on insulin ± oral than for those on oral(s) (p < 0.001). Regarding actual self-monitoring frequencies at steady state, 50% of HCPs believed patients on insulin ± oral tested less than recommended. Fewer HCPs (39%) believed that patients on oral(s) self-monitored less than recommended (p ≤ 0.05). In contrast, most patients (>70%) believed themselves compliant, regardless of therapy type. Most HCPs (>98%) would recommend that patients on the IMT self-monitor less than or the same as if they were on insulin ± oral, with the majority indicating that patients on IMT monitor less frequently. In comparison, most HCPs (>84%) would recommend that patients on IMT self-monitor the same as or more than if they were on oral(s), with the majority indicating that patients on IMT monitor the same as oral(s) only at steady state. CONCLUSIONS: HCPs recommend significantly more frequent self-monitoring for patients on insulin ± oral tested less than recommended. Fewer HCPs (39%) believed that patients on oral(s) self-monitored less than recommended (p ≤ 0.05). In contrast, most patients (>70%) believed themselves compliant, regardless of therapy type. Most HCPs (>98%) would recommend that patients on the IMT self-monitor less than or the same as if they were on insulin ± oral, with the majority indicating that patients on IMT monitor less frequently. In comparison, most HCPs (>84%) would recommend that patients on IMT self-monitor the same as or more than if they were on oral(s), with the majority indicating that patients on IMT monitor the same as oral(s) only at steady state. HCPs perceive patients on oral(s) to be more compliant to self-monitoring than those on insulin ± oral. Overall, patients see themselves as more compliant than do HCPs. The HCP recommended frequency for self-monitoring with the new IMT would lie between the recommended frequencies for oral(s) and insulin ± oral, but more similar to oral(s) at steady state.
OBJECTIVES: Updated risk equations are available for predicting outcome in people with type 2 diabetes (T2D): the UKPDS Outcomes Model (UKPDS 68). It is important to assess the validity of applying risk equations to populations other than those from which they were derived. The objective was to evaluate how well the UKPDS-68 equations predicted vascular morbidity and mortality in real-life data from Cardiff, UK, and compare estimates with the previous UKPDS Risk Engine equations (UKPDS-RE [from UKPDS publications 56 and 60]).

METHODS: The equations were incorporated into a stochastic simulation model that estimated the incidence and prevalence of complications (DiabForecaster). Predicted results from the model were compared with population data from Cardiff for coronary heart disease (CHD), stroke and all cause mortality. The annual incidence of newly diagnosed T2D, baseline modifiable risk factors and demographic profiles were matched to the Cardiff data. RESULTS: Internal validation, using a baseline cohort matched to the UKPDS study, demonstrated that the model predicted 12-year cumulative incidence in line with previous UKPDS publications. Real life and predicted event rates for CHD were: 116, 153 and 137 events/1000 T2D patients/yr for the Cardiff data, UKPDS-RE and UKPDS-68, respectively. For stroke: 178, 153 and 128 events/1000 T2D patients/yr, respectively. For all cause mortality: 418, 430, and 475 events/1000 T2D patients/yr, respectively. For all endpoints, predicted 12-year cumulative incidence in line with previous UKPDS publications. Real life and predicted event rates for CHD were: 116, 153 and 137 events/1000 T2D patients/yr for the Cardiff data, UKPDS-RE and UKPDS-68, respectively. For stroke: 178, 153 and 128 events/1000 T2D patients/yr, respectively. For all cause mortality: 418, 430, and 475 events/1000 T2D patients/yr, respectively.

CONCLUSIONS: All UKPDS equations demonstrated internal validity when compared with published UKPDS data, however both UKPDS-RE and UKPDS-68 equations over predicted the incidence of CHD and mortality and under predicted stroke. While all endpoints predicted were reasonably concordant with observational data discrepancies between UKPDS-68 and UKPDS-RE are worthy of further investigation.

PDB24

EFFECTS OF INDUCING CORRELATION AMONG CHOLESTEROL PARAMETERS ON OUTCOMES IN SIMULATION OF PHARMACEUTICAL EFFECTIVENESS
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OBJECTIVES: To determine whether inducing correlation among triglyceride, HDL, and LDL levels in a pharmaceutical treatment Monte Carlo simulation affects parameters’ means and variances; proportion with all parameters controlled; and summary statistics of estimated total cholesterol. METHODS: Means, standard deviations, and correlations among the cholesterol parameters were estimated from NHANES data for metabolic syndrome (MS) and diabetic patients with all parameters uncontrolled. For simulation, distributions were fit to the data. Analyses used 1000 replications of populations of 1000. Populations were generated without correlated parameters and with correlation induced in the uncorrelated data. Estimated changes with fenofibrate, statins, and a combination were taken from the literature. Total cholesterol was approximated using HDL, plus LDL, plus 20% of triglycerides. Differences in means and ratios of variances comparing uncorrelated and correlated results were calculated for each replication. Null hypotheses were rejected when the interval the middle 95% of replications spanned did not include zero for differences and one for ratios. RESULTS: Correlations were higher for diabetic than MS patients. Despite the data’s and distribution’s non-normality, induced correlations were close to NHANES correlations. Correlation did not affect the summary statistics of individual parameters or the proportion with all parameters under control. Correlation affected results for total cholesterol, the sum of other parameters. For MS, variance of total cholesterol was less than 7% lower with uncorrelated data than with correlated data. For diabetic patients, variance of total cholesterol was more than 20% higher with uncorrelated data. Findings held for subpopulations with and without all parameters controlled after taking medication. Variance results were similar across treatments. Total cholesterol means differed primarily for MS subgroups. CONCLUSIONS: Summary statistics (particularly variance) for sums of parameters are affected by correlation in Monte Carlo simulations. Underestimated and overestimated variances increase the risk of Type I and II error respectively.