from approximately 2.5 million patients. Data was extracted for insulin naive and prior insulin T2D patients initiated on basal insulin as monotherapy or as part of a basalo-sulfonylurea regimen in 2004–2006. RESULTS: The study included 7209 new basal insulin users, of which 4792 (67%) were insulin naive. Overall, 4728 (66%) used analogue with similar proportions using monotherapy (67%) and basal therapy (65%). The proportion of analogue users was greater among prior insulin users: 541 of 619 (87%) for monotherapy and 1331 of 1798 (74%) for basal insulin therapy compared with 2238 of 3702 (61%) and 598 of 1090 (55%) among naive users. Monotherapy for naive patients was initiated mainly by the GP (NP 70%, analogue 59%), for prior users mainly by the internist (NP 49%, analogue 59%), same as for basal-insulin users (NP 67–68%, analogue 75–80%). With NP, 22% discontinued their prescription (average of 220 days) and with basal analogues 17% (average of 230 days). Furthermore, 6% of patients on NP and 11% with basal analogues added-on to their prescription (after an average of 119 days and 126 days, respectively). Only 17% of patients switched treatment with basal analogues compared with NP (average of 190 days) versus 32% (average of 158 days), respectively.

CONCLUSIONS: When new insulin therapy is initiated, analogues are more often prescribed than NP, more frequently prescribed by Dutch internists and not discontinued or switched as frequently as NPH, indicating that basal insulin analogues give a more sustained and satisfactory result.

PAYING FOR COSTLY PHARMACEUTICALS—REIMBURSEMENT STATUS OF LONG-ACTING INSULIN ANALOGUES IN SELECTED DEVELOPED COUNTRIES

Mieczysław E. Orlewska1, Gulácsi L2
1Centrum Farmakoekonomiki, Warsaw, Poland, 2Corvinus University of Budapest, Budapest, Hungary

OBJECTIVES: Many aspects of the scientific, economic and political discussions on the benefit of new medicines, for which modern insulins are a pivotol example, influence recent decisions about drug reimbursement. This study was undertaken to compare the reimbursement status of long acting insulin analogues (LAIA) in several industrialized countries around the globe, where different criteria for public funding of pharmaceuticals have been used, but all include estimates of clinical effectiveness and/or cost effectiveness. METHODS: The study was performed based on a combination of desk research, direct contact with national diabetes stakeholders and expert review of reimbursement status questionnaires. In the first phase, information was gathered from each country on diabetes prevalence, cost, relevant policies and guidelines through a range of sources including government and patient association websites, published scientific literature, media reports. In the second phase additional information about reimbursement of LAIA was sought from recommendations obtained from government websites of HTA or similar agencies, or interviews carried out with national stakeholders representing health ministries, patient organisations or medical community. RESULTS: Fifteen countries have been included in the study (Australia, New Zealand, Canada, UK, The Netherlands, France, Germany, Austria, Sweden, Norway, Latvia, Lithuania, Estonia, Hungary, Bulgaria). Only in France LAIA are reimbursed in 65%, in all remained countries—in 100%. But in most countries there are several restrictions on access to LAIA, namely criteria for this type of treatment have been developed to respond the clinical and economic evidence (use in selected patients, application only from prescriber with referral letter, regular reassessments of metabolic control, listing after the company agreed to a price reduction). CONCLUSIONS: The story of LAIA is important not only because of the way the evidence has been interpreted, but because the voice of consultative bodies resulted in action by the health care purchasers.

HEALTH CARE UTILISATION AND EXPENDITURES ASSOCIATED WITH TREATMENT OF DIABETES MELLITUS WITHIN THE SLOVAK REPUBLIC

Teras T, Foltan V, Binder R
Comenius University, Bratislava, Slovak Republic

OBJECTIVE: The aim of this study was to collect comparable and reliable data about consumption of drugs for treatment of diabetes mellitus in Slovakia during the period 1999-2008. METHODS: Data of wholesalers (following ATC/DDD), who are legally obliged provide this information to the Slovak Institute for Drug Control, was used for the analysis. The results were expressed in the numbers of the packages, finance units (€) and defined daily doses per 1000 inhabitants per day (DID). RESULTS: The collected data shows a significant increases in the antidiabetics consumption from 1999 to 2008 in term of DID (in 1999 (33.34) and in 2008 (48.63)). A moderate increase in A10AB group (Insulins and analogues, fast-acting) in 1999 (3.03), in 2003 (3.47) and in 2008 (5.23), a significant decrease in A10AC group (Insulins and analogues, intermediate-acting) in 1999 (4.79), in 2003 (3.94) and in 2008 (2.20), a moderate increase in A10A8D (Insulins and analogues, intermediate-long-acting) in 1999 (2.71), in 2003 (4.05), a noticeable increase in A10AE (Insulins and analogues, long-acting) in 1999 (0.05), in 2003 (0.02) and in 2008 (1.09), a dramatic increase in A10BA (Biguanides) in 1999 (4.82), in 2003 (7.66) and in 2008 (13.51), a relatively stable consumption in A10BB (Sulfonylamides) in 1999 (17.57), in 2003 (15.87) and in 2008 (19.29) and a moderate increase in A10BD (Biguanides in combination) in 1999 (0.52), in 2003 (0.96) and in 2008 (1.68) in term of DID can be seen from this analysis. Financial expenditures for antidiabetics were in 1999 (159,271,000) and in 2008 (38,552,000). CONCLUSIONS: Inseparable components of the Slovak drug policy must be viewed realistically with regard to the antidiabetics’ consumption. Adherence to principles of diabetes mellitus treatment’s guidelines lead to fundamental short and long term financial savings within health care systems.
This paper studies the glycaemic and cholesterol control of type 2 diabetes patients in Singapore. National Healthcare Group (NHG) in Singapore treat over 11,000 patients with diabetes mellitus. The specialist outpatient clinics (SOCs) of the 3 acute hospitals of the National Healthcare Group (NHG) in Singapore treat over 11,000 patients with diabetes mellitus. This paper studies the glycaemic and cholesterol control of type 2 diabetes patients in Singapore. METHODS: This study was conducted to estimate quality adjusted life years (QALYs) loss due to morbidity of type 2 diabetes (T2D). We conducted manual searches of 54 health care agencies’ web sites for their HTA reports, a search was executed using the agencies websites with the following keywords: pioglitazone, rosiglitazone, sitagliptin, vildagliptin, exenatide, glargine, detemir, aspart, glulisine and lopid. If a report contained several drugs each drug was counted separately although a decision could involve parameters were clustered in three categories: efficacy, safety and health economics where each assessment could contain multiple parameters. Overall, recommendation was classified in three categories: recommended restricted recommended and not recommended in relation to indication based on marketing authorisation. RESULTS: 35 reports were identified with 49 assessments. Twelve assessments lead to recommendations (24%), 23 to restricted recommendation (47%) and fourteen to no recommendation (29%). Reasons for recommending a treatment contained in 83% of cases one or more arguments related to efficacy, 33% to safety, and 66% to health economic aspects of drugs. Reasons for restricted recommendation were 79%, 39%, and 60%, and for not recommended were 100%, 57% and 21% respectively. Within each decision parameter the most common reason for restricting the market authorization indication was related to the drug not being cost-effective (57%). The most common reason for not recommending a drug was lack of long term data on efficacy (86%). CONCLUSIONS: Despite that large variations in results between agencies were observed, data demonstrating efficacy of the drug appeared to be the most important factor in getting a recommendation for type 2 diabetes treatment. A high incremental cost-effectiveness ratio was likely to lead to restrictions in indication (NICE, SMC, and CVZ) whereas lack of long term data could lead to the drug not being recommended (IQWIG and CVZ).

**PDB71**

**GLYCAEMIC AND CHOLESTEROL CONTROL OF TYPE 2 DIABETIC PATIENTS ATTENDING SPECIALIST OUTPATIENT CLINICS IN SINGAPORE**

Lim BK1, Toh MPH2, Cheah TS3, Sam Choo P1, Jung M1, Choon SB1

1National Healthcare Group, Singapore, Singapore, 2Alexandra Hospital, Singapore, Singapore, 3Tan Tock Seng Hospital, Singapore, Singapore, 4National University Hospital, Singapore, Singapore

OBJECTIVES: The specialist outpatient clinics (SOCs) of the 3 acute hospitals of the National Healthcare Group (NHG) in Singapore are: (a) do poor compliance to diet; and (c) high cost of co-payment for medicines. CONCLUSIONS: Based on the results of the present study, physicians use insulin for T2D patients and they prefer OATs for TID. The economic burden of TID patients is heavy due to high co-payment rate, which might be linked to poorly regulated patients leading to higher incidence of diabetes-related complications.

**PDB72**

**QUALITY ADJUSTED LIFE YEARS LOSS DUE TO TYPE 2 DIABETES IN SOUTHERN KOREA**

Je MW1, Lee WJ1, Noh JH2, Choi Y3, Song KH4

1University of Seoul, Seoul, South Korea, 2Yonsei University IlSan Paik Hospital, Ilsan, Gyeonggi-Do, South Korea, 3Inje University Ilsan Paik Hospital, Ilsan, Gyeonggi-Do, South Korea, 4Kookmin University Hospital, Seoul, South Korea

OBJECTIVES: This study was conducted to estimate quality adjusted life years (QALYs) loss due to diabetes in type 2 diabetic patients of South Korea. METHODS: In order to obtain QALYs loss due to morbidity of type 2 diabetes (T2D), we firstly calculated utility weight difference between T2D patients and non-diabetic subjects by age and sex groups. We consecutively recruited T2D patients aged 20 or over who had visited three university hospitals in Seoul and Ilsan from October 2007 to January 2008 and non-diabetic subjects who took a medical examination from June 2008 to January 2009 in same hospitals. Utility weight differences on sex and age groups were calculated using the EuroQol. EQ-5D and Korean valuation set, and then QALY loss was estimated using the utilities and the number of T2D patients in 2003 reported by the Korean Diabetes Basic Statistics Study. QALY losses due to T2D mortality corresponded to life expectancy of the death caused to T2D life table and the Korean Death Certificate in 2003 multiplied by utility weights of healthy people by sex and age groups from the 3rd Korea National Health and Nutrition Examination Survey 2001-2002. We used a discount rate as 5%. RESULTS: Total 1,072 T2D patients and 387 non-diabetic subjects participated in this survey. Maximum difference between T2D patients and non-diabetic subjects was 0.0048 and minimum difference was -0.0039 by subgroups. QALY loss estimates due to T2D morbidity were about 35, 57 and 35, and 30, 613 QALYs in men and females respectively. Total death caused by T2D patients brought about 58,186 QALYs in men and 49,432 QALYs in females considering the discount rate. Therefore, total QALY loss was estimated as 193,336 QALYs annually. CONCLUSIONS: The results suggest that QALY loss estimates caused by T2D was 4.0 QALYs/1000 persons in South Korea at 2003.

**PDB73**

**ANALYSIS OF FACTORS INFLUENCING DECISION MAKING ON TYPE 2 DIABETES DRUGS IN 9 HTA-AGENCIES**

Adalsteinsson E1, Jensen RCØ2, Mondher T3, Hemels M4

1Novo Nordisk A/S, Bagvaard, Denmark, 2Københavns Universitet, København, Denmark, 3Novo Nordisk A/S, Bagvaard, Denmark, 4Kunkuk University Hospital, South Korea

OBJECTIVES: To map factors that influence HTA-agencies in their Health Technology Assessments (HTA) on type 2 diabetes agents in the UK (NICE), Scotland (SMC), The Netherlands, Germany (IQWIG) and Sweden (TLV). METHODS: To retrieve the HTA reports, a search was executed using the agencies websites with the following keywords: pioglitazone, rosiglitazone, sitagliptin, vildagliptin, exenatide, glargine, detemir, aspart, glulisine and lopid. If a report contained several drugs each drug was counted separately although a decision could involve parameters were clustered in three categories: efficacy, safety and health economics where each assessment could contain multiple parameters. Overall, recommendation was classified in three categories: recommended restricted recommended and not recommended in relation to indication based on marketing authorisation. RESULTS: 35 reports were identified with 49 assessments. Twelve assessments lead to recommendations (24%), 23 to restricted recommendation (47%) and fourteen to no recommendation (29%). Reasons for recommending a treatment contained in 83% of cases one or more arguments related to efficacy, 33% to safety, and 66% to health economic aspects of drugs. Reasons for restricted recommendation were 79%, 39%, and 60%, and for not recommended were 100%, 57% and 21% respectively. Within each decision parameter the most common reason for restricting the market authorization indication was related to the drug not being cost-effective (57%). The most common reason for not recommending a drug was lack of long term data on efficacy (86%). CONCLUSIONS: Despite that large variations in results between agencies were observed, data demonstrating efficacy of the drug appeared to be the most important factor in getting a recommendation for type 2 diabetes treatment. A high incremental cost-effectiveness ratio was likely to lead to restrictions in indication (NICE, SMC, and CVZ) whereas lack of long term data could lead to the drug not being recommended (IQWIG and CVZ).

**PDB74**

**ETHICAL DILEMAS OF PHARMACOLOGICAL TREATMENT AND SELF MANAGEMENT OF DIABETES—A REVIEW OF THE LITERATURE**

Jensen RCØ1, Kaas C2, Mondher T3, Hemels M4

1University of Copenhagen, Copenhagen, Denmark, 2Copenhagen University Hospital, Copenhagen, Denmark, 3Novo Nordisk A/S, Bagvaard, Denmark

OBJECTIVES: There is increasing focus on the ethical analysis in Health Technology Assessments (HTAs). Due to the ethical issues involved in diagnosis and treatment of diabetes, there is an urgent health concern. We therefore systematically reviewed published articles describing the ethical aspects of pharmacological treatment and self management of diabetes. METHODS: PubMed was searched from inception to 2009 using the following combinations of keywords: ethics AND diabetes NOT screening NOT transplant. Articles were initially screened for relevance by reading title and abstract. If deemed appropriate, by two independent reviewers, full copies of the remaining articles were retrieved for further review. RESULTS: Out of 336 articles, only six studies were deemed appropriate. The main reason for this high level of rejected articles was that the majority of identified articles commented on the ethical approval in connection to conducting clinical studies rather than on the ethical aspects of implementing and using the specific technology. One study described the ethical concern related to the costly late complications of diabetes compared to preventing late complications by prescribing and reimbursing insulin. Other ethical issues concerned self management and the transferal of responsibility from physician to patient and the patient’s capabilities for self management. For people with impaired glucose tolerance there were also ethical issues related to initiating a preventive pharmaceutical treatment of the “otherwise well”. Lastly, there is an ethical issue between the transformative gold standard for a healthy and moral lifestyle and a culture of self that values authenticity and originality. CONCLUSIONS: Due to the escalating prevalence of diabetes and emphasis on ethical analysis in HTAs, both parties and the industry needs to get a better understanding of the ethical aspects of self management and pharmaceutical treatment of diabetes. More research should be allocated towards investigating the ethical aspects of self management and pharmaceutical treatment of diabetes.

**PDB75**

**APPLICATION OF HTA TO ANTIDIABETIC DRUG FORMULARY DECISIONS**

Andrakopoulou M, Wiberg C

Quintiles Consulting, Hoofddorp, The Netherlands

OBJECTIVES: To compare Health Technology Assessments (HTAs) and reimbursement decisions of a novel antidiabetic drug class, by health care agencies worldwide. METHODS: We conducted manual searches of 54 health care agencies’ web sites from January 2008 to May 2009. HTAs regarding diabetes were collected and each was assessed for date, type (e.g., single drug versus class review) and scope (e.g., medicine name). Using a standardized set of categorial criteria, we investigated recommendations, as well as presence of supporting evidence (e.g., reported outcome measures, information sources, and key decision drivers). RESULTS: A total of 21 completed diabetes assessments were assessed. Data were retrieved from 9 agencies in 9 countries. The agencies published 21 assessments on diabetes during the review period; including 4 clinical guidelines, 9 single drug appraisals and 8 class reviews. Of