

Basal insulin initiation in primary vs. specialist care: similar glycaemic control in two different patient populations

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SUMMARY

Objective: To investigate the effect of healthcare provider (HCP) type (primary vs. specialist) on glycaemic control and other treatment parameters. **Research design and methods:** Study of Once-Daily Levemir (SOLVE™) is an international, 24-week, observational study of insulin initiation in people with type 2 diabetes. **Results:** A total of 17,374 subjects were included, comprising 4144 (23.9%) primary care subjects. Glycaemic control improved in both HCP groups from baseline to final visit [glycated haemoglobin (HbA1c) $-1.2 \pm 1.4\%$ (-13.1 ± 15.3 mmol/mol) and $-1.3 \pm 1.6\%$ (-14.2 ± 17.5 mmol/mol), respectively]. After adjustment for known confounders, there was no statistically significant effect of HCP group on final HbA1c [-0.04% , 95% confidence interval (CI) -0.09 to -0.01 (-0.4 mmol/mol, 95% CI -1.0 – 0.1 mmol/mol), $p = 0.1590$]. However, insulin doses at the final visit were higher in primary care patients ($+0.06$, 95% CI 0.06 – 0.07 U/kg, $p < 0.0001$). Logistic regression demonstrated a significant effect of HCP type (primary vs. specialist care) on hypoglycaemia risk [odds ratio (OR) 0.75 , 95% CI 0.64 – 0.87 , $p = 0.0002$]. Primary care physicians took more time to train patients and had more frequent contact with patients than specialists (both $p < 0.0001$). **Conclusions:** Primary care physicians and specialists achieved comparable improvements in glycaemic control following insulin initiation.

Introduction

Type 2 diabetes care is increasingly managed in primary care (1). The high and increasing prevalence of type 2 diabetes and the strain on limited specialist resources determine the involvement of primary care (2). This transition to primary care has not been without controversy, and the impact on mortality, risk factor control (including glycaemic control, blood pressure, lipid control and weight management) (3), processes [such as frequency of glycated haemoglobin (HbA1c) testing, initiation of risk factor preventative therapy] (4) and resource use (5,6) have been scrutinised. However, primary-based structured care can achieve the quality of care comparable with international best practice standards, despite limited investment (7).

Regimen adherence is known to be poor in chronic medical conditions, such as type 2

diabetes, and for self-care behaviours like diet and exercise (8). Improved accessibility to physicians (e.g. through primary care services) might be expected to encourage greater therapy adherence, and there is a greater opportunity for therapeutic intervention, monitoring and titration (3,6,9,10). In addition, implementation of patient-driven insulin treatment algorithms in primary care may be easier with the improved safety profiles of basal insulin analogues (11). However, primary care physicians often have concerns about the resources required and unfamiliarity with initiating insulin therapy (6).

In this study, the demography, therapeutic management and outcomes of patients managed by primary and specialist care practitioners during insulin initiation are described and compared, using data collected from a large, international observational study.

What's known

- Subjects with type 2 diabetes are being increasingly managed in primary care as opposed to specialist care. The impact on mortality, risk factor control and resource use between these two types of care is continuously under assessment.
- Primary care physicians often have concerns regarding the unfamiliarity and the resources required when initiating insulin therapy.

What's new

- From a large, international, observational cohort, this analysis shows that primary and specialist care achieved comparable improvements in HbA1c in subjects with type 2 diabetes who initiated and maintained treatment with basal insulin for 24 weeks.
- Differences were reported between primary and specialist care in terms of insulin dose, the risk of hypoglycaemia, and resource utilisation.
- The findings provide reassurance for primary care management of subjects with type 2 diabetes.

Research design and methods

The Study of Once-Daily Levemir (SOLVE™) is a large, international, non-interventional study that enrolled and prospectively followed people with type 2 diabetes who were under primary care and specialist care. The study was conducted in 10 countries: Canada, China, Germany, Israel, Italy, Poland, Portugal, Spain, Turkey and the UK. The study was pre-registered with ClinicalTrials.gov (NCT00825643 and NCT00740519) and was approved by local ethics committees in each of the participating countries.

Details of the study methodology have been reported previously (12). Patients were eligible for study inclusion if they were > 18 years of age, had a diagnosis of type 2 diabetes, and a decision had already been made to initiate insulin using once-daily insulin detemir. Other inclusion criteria differed between countries because of local regulatory and ethics requirements, which were described previously (12). Subjects were excluded if they became pregnant or were intending to become pregnant, deviated from the once-daily insulin regimen using more frequent basal insulin administration or added bolus insulin. Data were collected from case notes and measurements were made as close as possible to three time points: immediately prior to insulin initiation (preinsulin) and at 12- and 24-week follow-ups. The primary study endpoint was the incidence of severe adverse drug reactions and/or severe hypoglycaemia. Secondary endpoints also included measurements of glycaemic efficacy (e.g. HbA1c), safety (e.g. minor hypoglycaemia and weight) and health resource use. Severe hypoglycaemia was defined as a hypoglycaemic event requiring third-party assistance, and minor hypoglycaemia was defined as measured blood glucose ≤ 3.9 mmol/l (≤ 56 mg/dl), with or without symptoms.

The study had no prescribed procedures, and all management decisions were entirely at the discretion of the treating healthcare provider (HCP). In the UK, HCPs included specialist diabetes nurses. In all other countries, care was provided by primary or specialist care physicians.

Statistical analysis

Continuous data are presented as the mean with standard deviation, and categorical data are presented as the frequency and percentage. Baseline group comparisons were made using an unpaired *t*-test and chi-square analyses for continuous and categorical data, respectively. HbA1c values were converted from Diabetes Control and Complications Trial-derived to International Federation of Clinical Chemistry recommended units (13).

Because this was a non-randomised study, regression models were used to describe the effect of patients being managed in primary vs. specialist care, adjusting for several previously identified confounders. Models of HbA1c at the final visit and the odds of at least one hypoglycaemic episode (mild or severe) included the following parameters: age category (< 50 years, 50–75 years in 5-year intervals and ≥ 75 years), diabetes duration (in quartiles), body mass index (BMI) category (< 25 kg/m², 25 to < 30 kg/m², 30 to < 35 kg/m² and ≥ 35 kg/m²), previous history of hypoglycaemia or microvascular disease, number and change in oral antidiabetic drug (OAD) therapy at the time of insulin initiation, HbA1c at baseline and insulin dose (U in quartiles). The odds of weight loss ≥ 1 kg included the following parameters: sex, BMI (categories as described above), number of OADs at baseline and baseline HbA1c. The model of insulin dose at the final visit included adjustment for duration of diabetes and weight at baseline. These regression models have been described previously (14,15). All regression models included the additional variable, HCP type, to denote treatment by a primary or specialist care physician.

Missing data were not imputed and the level of significance was set at $\alpha = 0.05$. All analyses were performed using Statistical Analysis Software version 9.1 or newer (SAS Institute, Cary, NC, USA).

Results

A total of 17,374 subjects were included in the analysis, comprising 4144 (23.9%) subjects managed in primary care and 13,230 (76.1%) subjects managed in specialist care (Table 1). Out of the five highest-recruiting countries, an average of 12.6% of patients were recruited from primary care, with four countries (Italy, China, Israel and Poland) not enrolling any patients from primary care (Table S1).

Baseline characteristics

There were significant differences between the primary and specialist care cohorts at baseline (Table 1). The primary care group of patients were older, had a higher BMI and had a shorter history of OAD treatment despite having a similar duration of diabetes compared with the specialist care group. A larger proportion of patients managed in primary care also had a previous history of macrovascular disease and hypoglycaemia. The overall incidence of hypoglycaemia prior to insulin therapy was low, and glycaemic control was similar between the primary and specialist care groups (Table 1). A larger proportion of patients were

Table 1 Baseline characteristics by healthcare provider group

| | Cohort | | p value |
|-------------------------------------|-------------------------|-------------------------|----------|
| | Primary care | Specialist care | |
| N (%) | 4144 (23.9) | 13,230 (76.1) | |
| Age (years) | 63.5 ± 11.6 | 61.0 ± 11.4 | < 0.0001 |
| Male (%) | 2181 (52.7) | 7008 (53.0) | 0.7645 |
| Ethnicity (%) | | | |
| White | 3018 (81.6) | 9235 (72.0) | < 0.0001 |
| Black | 73 (2.0) | 44 (0.3) | |
| Other | 608 (16.4) | 3546 (27.6) | |
| Duration of diabetes (years) | 9.5 ± 6.6 | 9.8 ± 7.2 | 0.1313 |
| Duration of OAD treatment (years) | 7.9 ± 6.0 | 8.6 ± 6.8 | < 0.0001 |
| Previous medical history (%) | | | |
| Macrovascular complications | 1211 (30.4) | 3331 (25.5) | < 0.0001 |
| Microvascular complications | 1310 (32.7) | 4320 (33.0) | 0.6688 |
| Hypoglycaemia | 229 (5.6) | 620 (4.7) | 0.0253 |
| Severe hypoglycaemia (events ppy) | 0.075 ± 1.389 | 0.036 ± 0.687 | 0.0436 |
| Minor hypoglycaemia (events ppy) | 2.429 ± 26.450 | 1.332 ± 13.211 | 0.0765 |
| Weight (kg) | 87.7 ± 19.6 | 78.8 ± 16.5 | < 0.0001 |
| BMI (kg/m ²) | 30.9 ± 5.6 | 28.8 ± 5.2 | < 0.0001 |
| FBG (mg/dl) [mmol/l] | 187 ± 54 [10.4 ± 3.0] | 186 ± 56 [10.3 ± 3.1] | 0.2034 |
| HbA1c (%) [mmol/mol] | 8.9 ± 1.6 [74.0 ± 17.5] | 8.9 ± 1.6 (74.0 ± 17.5) | 0.7210 |
| Number of OADs | | | |
| 1 | 1595 (39.5) | 3505 (26.9) | < 0.0001 |
| 2 | 1892 (46.9) | 7352 (56.3) | |
| > 2 | 547 (13.6) | 2193 (16.8) | |
| Types of OADs | | | |
| Biguanide | 3359 (83.3) | 10,536 (80.7) | 0.0003 |
| Sulphonylureas | 1980 (49.1) | 8160 (62.5) | < 0.0001 |
| Glinides | 483 (12.0) | 2265 (17.4) | < 0.0001 |
| α-glucosidase inhibitors | 149 (3.7) | 1931 (14.8) | < 0.0001 |
| Thiazolidinediones | 449 (11.1) | 1626 (12.5) | 0.0239 |
| Dipeptidyl-peptidase IV inhibitors | 633 (15.7) | 474 (3.6) | < 0.0001 |
| Any lipid-lowering drug treatment | 1866 (59.5) | 4784 (40.2) | < 0.0001 |
| Any antihypertensive drug treatment | 2634 (76.3) | 7439 (58.7) | < 0.0001 |

Continuous variables are given as mean ± SD and categorical variables as number (%). BMI, body mass index; FBG, fasting blood glucose; HbA1c, glycated haemoglobin; OAD, oral antidiabetic drug; ppy, per patient year; SD, standard deviation.

managed using a single oral agent prior to insulin initiation in the primary care group compared with the specialist care group (39.5% vs. 26.9%, $p < 0.0001$). The use of sulphonylureas, glinides, α-glucosidase inhibitors and thiazolidinediones was significantly lower in primary vs. specialist care, with the largest difference being the sulphonylureas (49.1% vs. 62.5%, respectively, $p < 0.0001$). The use of metformin and dipeptidyl-peptidase IV (DPP-IV) inhibitors was significantly higher in primary care, with 15.7% using DPP-IV inhibitors vs. + 3.6% in specialist care ($p < 0.0001$). A higher proportion of patients managed in primary care were also receiving lipid-lowering and antihypertensive treatment (both $p < 0.0001$).

Glycaemic control, insulin doses, weight and hypoglycaemia during the study

At baseline, the levels of HbA1c and fasting blood glucose were similar between both groups (Table 1). After 24 weeks of treatment, there were significant improvements in glycaemic control from baseline in both primary and specialist care cohorts [change in HbA1c $-1.2 \pm 1.4\%$ (-13.1 ± 15.3 mmol/mol) and $-1.3 \pm 1.6\%$ (-14.2 ± 17.5 mmol/mol), respectively, both $p < 0.001$]. The change in fasting blood glucose was -52 ± 49 mg/dl (-2.9 ± 2.7 mmol/l) and -56 ± 54 mg/dl (-3.1 ± 3.0 mmol/l) in the primary and specialist groups, respectively] (Table 2). Insulin doses increased from 13 ± 7 U at baseline to 27 ± 22 U at final visit in the group managed in pri-

primary care ($p < 0.001$) and from 13 ± 6 to 20 ± 12 U in the group managed by specialist care ($p < 0.001$). Patients from the primary care group had greater weight at baseline compared with the specialist care group ($p < 0.0001$, Table 1), but in both groups, there was a mean weight reduction from baseline after 24 weeks of treatment (-1.1 ± 8.1 and -0.4 ± 4.7 kg, respectively, both $p < 0.001$) (Table 2). At baseline, patients from primary and specialist care groups had different incidence rates of severe hypoglycaemia ($p = 0.0436$) and similar rates of minor hypoglycaemia ($p = 0.0765$) (Table 1). After 24 weeks of treatment, the change relative to baseline in the incidence of severe hypoglycaemia was -0.051 events per patient year in the primary care group and -0.028 events per patient year in the specialist care group ($p < 0.001$) (Table 2). The incidence of minor hypoglycaemia in patients managed in primary care was similar to baseline (-0.08 events per patient year, $p = 0.788$), whereas the incidence of minor hypoglycaemia increased from baseline in the group of patients managed in specialist care ($+0.36$ events per patient year, $p < 0.001$).

Table 3 shows the effect of HCP type on HbA1c at the final visit, insulin dose at the final visit, the

odds of one or more episodes of hypoglycaemia and the odds of weight loss ≥ 1 kg, following adjustment for previously identified confounders. The analyses show that there was no effect of HCP type on the level of glycaemic control attained at the final visit [HbA1c -0.04% , 95% confidence interval (CI) -0.09 to 0.01 (-0.4 mmol/mol, 95% CI -1.0 to 0.1 mmol/mol), $p = 0.1590$ for primary vs. specialist care]. Also, the odds of weight loss ≥ 1 kg were not statistically different in primary care compared with specialist care [odds ratio (OR) 1.07 , 95% CI 0.98 – 1.16 , $p = 0.1409$]. Insulin doses, however, were higher in patients managed in primary care ($+0.06$, 95% CI 0.06 – 0.07 U/kg, $p < 0.0001$), and logistic regression also demonstrated a significant effect of HCP type on the risk of hypoglycaemia. The odds of at least one hypoglycaemic episode were lower in primary care compared with specialist care (OR 0.75 , 95% CI 0.64 – 0.87 , $p = 0.0002$).

OAD management following insulin initiation

Insulin was most commonly used in combination with a single oral agent for patients managed in primary care, whereas for patients managed in

Table 2 Glycaemic control, weight, hypoglycaemia incidence and insulin dose by healthcare provider group after 24 weeks of treatment

| | Cohort | |
|---|---------------------------------------|--|
| | Primary care | Specialist care |
| Glycaemic control | | |
| HbA1c (%) [mmol/mol] | | |
| Final visit | 7.6 ± 1.2 [60.0 \pm 13.1] | 7.5 ± 1.2 [58.0 \pm 13.1] |
| Change from baseline | $-1.2 \pm 1.4^*$ [-13.1 ± 15.3] | $-1.3 \pm 1.6^*$ [-14.2 ± 17.5] |
| FBG (mg/dl) [mmol/l] | | |
| Final visit | 133 ± 40 [7.4 \pm 2.2] | 130 ± 34 [7.2 \pm 1.9] |
| Change from baseline | -52 ± 49 [-2.9 ± 2.7] | -56 ± 54 [-3.1 ± 3.0] |
| Insulin dose (U) | | |
| Insulin initiation | 13 ± 7 | 13 ± 6 |
| Final visit | 27 ± 22 | 20 ± 12 |
| Change from baseline | $+14 \pm 22^*$ | $+7 \pm 12^*$ |
| Weight (kg) | | |
| Final visit | 86.7 ± 18.5 | 78.2 ± 15.8 |
| Change from baseline | $-1.1 \pm 8.1^*$ | $-0.4 \pm 4.7^*$ |
| Hypoglycaemia incidence (events ppy) | | |
| Severe hypoglycaemia | | |
| Final visit | 0.027 ± 0.947 | 0.005 ± 0.224 |
| Change from baseline | -0.051 CI [-0.108 to 0.005] | -0.028^* CI [-0.040 to -0.015] |
| Hypoglycaemia incidence (events ppy) | | |
| Minor hypoglycaemia | | |
| Final visit | 2.086 ± 25.162 | 1.749 ± 9.633 |
| Change from baseline | -0.083 CI [-1.250 to 1.085] | $+0.362^*$ CI [0.052 – 0.672] |

FBG, fasting blood glucose; HbA1c, glycated haemoglobin; ppy, per patient year. * $p < 0.001$ for change from baseline.

Table 3 Effect of healthcare provider on HbA1c at final visit (%), insulin dose (U/kg), odds of at least one hypoglycaemia event [odds ratio (OR)] and odds of weight loss of ≥ 1 kg during study (OR)

| | Effect size | 95% confidence limits | p value |
|--|--------------|-----------------------------|----------|
| HbA1c (%) [mmol/mol]* | | | |
| Primary care vs. specialist care | -0.04 [-0.4] | -0.09 to +0.01 [-1.0, +0.1] | 0.1590 |
| Insulin dose (U/kg)[†] | | | |
| Primary care vs. specialist care | +0.06 | +0.06 to +0.07 | < 0.0001 |
| Hypoglycaemia event (OR)* | | | |
| Primary care vs. specialist care | 0.75 | 0.64–0.87 | 0.0002 |
| Weight loss ≥ 1 kg (OR)[‡] | | | |
| Primary care vs. specialist care | 1.07 | 0.98–1.16 | 0.1409 |

*Adjusted for age category (< 50 years, 50–75 years in 5-year intervals and ≥ 75 years), diabetes duration (in quartiles), BMI category (< 25 kg/m², 25 to < 30 kg/m², 30 to < 35 kg/m² and ≥ 35 kg/m²), previous history of hypoglycaemia or microvascular disease, number and change in OAD therapy at the time of insulin initiation, HbA1c at baseline and insulin dose (U in quartiles).

[†]Adjusted for diabetes duration and weight at baseline. [‡]Adjusted for gender, BMI (as presented above), number of OADs at baseline and baseline HbA1c. BMI, body mass index; HbA1c, glycated haemoglobin.

specialist care, most patients were prescribed insulin in addition to at least two oral agents ($p < 0.0001$; Table 4). In general, the proportion of patients using each class of OAD decreased following the addition of insulin, with the exception of metformin and DPP-IV inhibitors (which remained similar to baseline) in patients managed by primary care, and glinides and α -glucosidase inhibitors (which increased from baseline) in patients managed by specialist care.

Physician resource utilisation

The majority of primary and specialist care physicians felt confident about the patients' ability to

self-inject and self-titrate the basal insulin dose (91.8% and 95.7%, respectively) (Table S2). More time was taken in primary care than in specialist care to train patients to self-inject (18 ± 16 min vs. 14 ± 12 min, $p < 0.0001$), adjust doses (13 ± 13 min vs. 11 ± 10 min, $p < 0.0001$) and for other aspects of insulin treatment (22 ± 26 min vs. 16 ± 14 min, $p < 0.0001$). There was also evidence of more frequent face-to-face contact with patients in the group managed by primary care compared with specialist care (3.0 ± 2.5 vs. 1.7 ± 2.0 office contacts at the interim visit, respectively, and 2.3 ± 2.3 vs. 1.4 ± 1.7 office contacts at the final visit, respectively; $p < 0.0001$). There were also a

Table 4 Number and type of concomitant OAD, lipid-lowering and antihypertensive treatment at final visit, according to healthcare provider group

| | Cohort | | p value |
|-------------------------------------|--------------|-----------------|----------|
| | Primary care | Specialist care | |
| Number of OADs (%) | | | |
| 1 | 2119 (60.7) | 4031 (36.1) | < 0.0001 |
| 2 | 1178 (33.8) | 5875 (52.7) | |
| > 2 | 152 (4.4) | 1206 (10.8) | |
| Types of OADs (%) | | | |
| Biguanide | 2889 (83.8) | 8651 (77.9) | < 0.0001 |
| Sulphonylureas | 970 (28.1) | 5413 (48.7) | < 0.0001 |
| Glinides | 332 (9.6) | 2468 (22.2) | < 0.0001 |
| α -glucosidase inhibitor | 60 (1.7) | 1726 (15.5) | < 0.0001 |
| Thiazolidinediones | 152 (4.4) | 976 (8.8) | < 0.0001 |
| Dipeptidyl-peptidase IV inhibitors | 528 (15.3) | 249 (2.2) | < 0.0001 |
| Any lipid-lowering drug treatment | 1543 (61.2) | 4321 (43.2) | < 0.0001 |
| Any antihypertensive drug treatment | 2321 (78.1) | 6590 (60.0) | < 0.0001 |

OAD, oral antidiabetic drug.

greater number of dose adjustments in the primary care compared with the specialist care group (4.8 ± 7.5 vs. 2.6 ± 3.6 dose adjustments at the interim visit, respectively, and 2.9 ± 5.0 vs. 1.9 ± 2.5 dose adjustments at the final visit, respectively, $p < 0.0001$).

Discussion

This subanalysis of a large, international, observational study showed several baseline demographic differences between patients who were initiating basal insulin therapy in primary and specialist care, particularly with respect to weight and the number and type of OADs prescribed. Patients managed by specialists were younger and leaner and had fewer macrovascular complications, but a longer duration of OAD treatment. Although it is clear that patients are different in primary care and specialised care, these possible confounders could be adjusted by statistics analysis.

Glycaemic control, insulin doses, weight and hypoglycaemia during the study

There were no significant effects of HCP type on glycaemic control and weight loss ≥ 1 kg, despite a statistically significant but clinically small increase in insulin dose in the primary care group of patients. After adjustment for known confounders, the risk of at least one hypoglycaemic episode was significantly higher in patients who were managed in specialist care.

The higher risk of minor hypoglycaemia in the specialist care group may reflect differences in the case mix between the two HCP groups—the more complex and difficult-to-treat patients are managed by specialists rather than primary care practitioners (i.e. confounding by indication) (5,16–19). Weight, which is known to be protective of insulin-induced hypoglycaemia (20), was significantly lower in the group receiving specialist care. The higher proportion of patients continuing to use oral agents such as sulphonylureas and glinides, which are known to be associated with a higher risk of hypoglycaemia relative to other oral agents, may have been a contributing factor in the group receiving specialist care.

OAD management following insulin initiation

When the individual classes of OADs were examined, it was found that patients managed by specialists were using fewer DPP-IV inhibitors and more sulphonylureas, glinides and α -glucosidase inhibitors. As in specialist care insulin was prescribed most commonly in addition to at least two oral agents, it

was more likely that patients would receive drugs other than biguanides. In the present study, the use of DPP-IV inhibitors was higher in the primary care group. These numbers may indicate differences in availability and reimbursement of DPP-IV inhibitors between participating countries, but they may also indicate that primary care providers tend to use agents with perceived lower hypoglycaemia risk and/or are quicker to adopt novel treatments than previously reported (21,22).

Patients in the specialised care group had a longer duration of OAD therapy and higher use of secretagogues, which are known to have higher monotherapy failure rates (23,24). Perhaps, these patients are also more likely to be referred to a specialist by primary care physicians who do not usually prescribe insulin. However, the level of glycaemic control achieved by both the primary and specialist care groups was similar at the final visit, and insulin doses were lower in the group of patients managed by specialist care. In addition, the effects of individual oral agents were not included in regression models.

Physician resource utilisation

The management of diabetes is associated with an increase in healthcare resources that may begin 24 months before the diagnosis (2). In the present study, primary care allowed more time to train patients, and there was also evidence of more frequent face-to-face contact with patients in the group managed by primary care compared with specialist care. These factors may have contributed to a greater number of dose adjustments in the primary care group. As in the present study, Harris et al. (11) reported higher basal insulin analogue doses in patients managed in primary care compared with those patients managed by specialists, but there was a higher concomitant use of OADs among patients managed by specialists.

Although follow-up has been shown to be better in specialist clinics compared with primary care (18), other authors reported that specialist care did not improve survival in adults with diabetes cared for in ambulatory care settings (25). McAlister's study cohort (1991–2001) predates the Action to Control Cardiovascular Risk in Diabetes study, which also reported a survival disadvantage in patients receiving intensive glycaemic [mean HbA1c 6.4% (46 mmol/mol)] vs. standard glycaemic [mean HbA1c 7.5% (58 mmol/mol)] control (26).

In addition, there have been continual improvements in the primary care management of type 2 diabetes. In Spain, for example, primary care centres, which are similar to those participating in the

present study, demonstrated significant improvements between 1993 and 2007 in process measures (such as measurement of HbA1c and lipid levels), intermediate outcome measures [including the proportion of patients with HbA1c $\leq 7.0\%$ (53 mmol/mol), total cholesterol ≤ 200 mg/dl and blood pressure $\leq 140/90$ mmHg], and microvascular complications (27,28). Primary care-led structured care, with relatively limited but well-focussed investment, can achieve quality of care for patients with diabetes, comparable to international best practice (7). The organisation of primary care service provision for diabetes continues to evolve. Structured care with computerised central recall systems, which have been shown to achieve standards of care that are equivalent to, or better than, hospital outpatient care (29,30), are gradually replacing unstructured community-based care by individual primary care physicians (31). However, there have been no improvements in biomedical outcomes as a result of structured care (32–34), and a significant proportion of patients with type 2 diabetes probably still underuse healthcare services (35). Also, to improve access to specialists for new patients, an efficient and appropriate discharge process is required. It is important to prepare patients for discharge from care and to recognise that individual patients have varying needs and preferences (36).

Thus, whether or not specialists are more likely to implement processes of care, these differences are generally small compared with the overall deficiencies in the quality of healthcare provision (37). Therefore, future research should instead focus on ways to implement high quality care, regardless of type of HCP.

Limitations

There are important limitations to this study. As this was an observational study, any differences between the primary care and specialist care groups may be the result of unmeasured confounding variables. The effect of HCP type on HbA1c, hypoglycaemia and weight was examined using regression analyses including several known confounders. However, four out of five of the largest-recruiting countries were managed entirely by specialist care physicians, and this constitutes a selection bias. It is uncertain how these differences in the involvement of primary and specialist care in each of the participating countries would influence the results of this analysis. Because the interaction between primary and specialist care tends to be specific to each country, it will be

important to validate the results reported here in each individual country.

More effective collaboration between primary and specialist caregivers is still required to avoid delays in appropriate treatment intensification (9,38). Better collaboration between primary and specialist caregivers (e.g. facilitating interactive communication and the use of interdisciplinary diabetes care teams) is considered to be one of the most important ways to improve insulin treatment in patients with type 2 diabetes (39–41).

In summary, we showed similar glycaemic control without increased risk of hypoglycaemia following initiation of basal insulin analogue treatment in patients managed in primary care compared with specialist care, which provides strong reassurance that the transition of insulin initiation from specialist to primary care has been successful. Primary care is a necessary and able partner in providing type 2 diabetes care. Future research should focus on ways to facilitate collaboration between primary and specialist caregivers.

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Author contributions

D.O.B. is guarantor for the manuscript. D.O.B. conceived the SOLVE data analysis and manuscript proposal, outlined the discussion, and reviewed/edited the manuscript. S.C. contributed to the discussion and reviewed/edited the manuscript. C.P. reviewed and edited the manuscript. A.L.S. researched data and reviewed/edited the manuscript. L.F. contributed to the discussion and reviewed/edited the manuscript. D.O.B., S.C. and C.P. were principal investigators of the study, provided input to the study protocol and were responsible for study implementation in their respective countries. All authors had access to the study data that support the publication.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Participation by country.

Table S2. Physician resource utilisation at baseline and final visit according to healthcare provider group.

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