# Effectiveness of a Regional Prepregnancy Care Program in Women With Type 1 and Type 2 Diabetes

## Benefits beyond glycemic control

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**OBJECTIVE** — To implement and evaluate a regional prepregnancy care program in women with type 1 and type 2 diabetes.

**RESEARCH DESIGN AND METHODS** — Prepregnancy care was promoted among patients and health professionals and delivered across 10 regional maternity units. A prospective cohort study of 680 pregnancies in women with type 1 and type 2 diabetes was performed. Primary outcomes were adverse pregnancy outcome (congenital malformation, stillbirth, or neonatal death), congenital malformation, and indicators of pregnancy preparation (5 mg folic acid, gestational age, and A1C). Comparisons were made with a historical cohort ($n$ = 613 pregnancies) from the same units during 1999–2004.

**RESULTS** — A total of 181 (27%) women attended, and 499 women (73%) did not attend prepregnancy care. Women with prepregnancy care presented earlier (6.7 vs. 7.7 weeks; $P < 0.001$), were more likely to take 5 mg preconception folic acid (88.2 vs. 26.7%; $P < 0.0001$) and had lower A1C levels (A1C 6.9 vs. 7.6%; $P < 0.0001$). They had fewer adverse pregnancy outcomes (1.3 vs. 7.8%; $P = 0.009$). Multivariate logistic regression confirmed that in addition to glycemic control, lack of prepregnancy care was independently associated with adverse outcome (odds ratio 0.2 [95% CI 0.05–0.89]; $P = 0.03$). Compared with 1999–2004, folic acid supplementation increased (40.7 vs. 32.5%; $P = 0.006$) and congenital malformations decreased (4.3 vs. 7.3%; $P = 0.04$).

**CONCLUSIONS** — Regional prepregnancy care was associated with improved pregnancy preparation and reduced risk of adverse pregnancy outcome in type 1 and type 2 diabetes. Prepregnancy care had benefits beyond improved glycemic control and was a stronger predictor of pregnancy outcome than maternal obesity, ethnicity, or social disadvantage.

*Diabetes Care* **33:2514–2520, 2010**

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Received 10 June 2010 and accepted 10 August 2010.

The views expressed in this publication are those of the authors and not necessarily those of the NHS, NIHR, or Department of Health.

DOI: 10.2337/dc10-1113



**See accompanying editorial, p. 2713.**

Rates of adverse pregnancy outcome (congenital malformation, stillbirth, or neonatal death) in women with diabetes are three to five times greater than those of the background maternity population (1,2). It is therefore recommended that all women of reproductive age with diabetes are offered annual preconception counseling and advised to avoid unplanned pregnancy (3). Prepregnancy care is the targeted support and additional clinical care offered to women planning pregnancy.

It is well established that for women with type 1 diabetes, specialist prepregnancy care improves glycemic control and reduces adverse pregnancy outcomes (4–11). Yet, despite documented benefits in selected centers of excellence, only two regional programs have been described, both almost 20 years ago (4,11). Failure to improve prepregnancy care provision leaves a majority of women at increased risk of potentially preventable poor pregnancy outcomes. This was confirmed by the Confidential Enquiry for Maternal and Child Health, revealing that only 17% of U.K. maternity units offer prepregnancy care and that only 10% of women, mostly those with type 1 diabetes, attend (12).

Type 2 diabetes has now emerged as a growing concern in pregnancy (13). Women with type 2 diabetes are predominantly cared for in community settings and are unlikely to access specialist prepregnancy care. Studies (12,14–16) from the U.K., France, and Denmark demonstrate a clear association between poor pregnancy preparation and adverse pregnancy outcomes in type 2 diabetes. Women with type 2 diabetes also tend to be older, more obese, more ethnically diverse, more socially disadvantaged, and more likely to have concomitant comorbidities, factors that are all associated with poor pregnancy outcome (12).

The additional health inequalities, obesity, and obstetric risk factors of women with type 2 diabetes are not easily overcome by prepregnancy care. However, women with type 2 diabetes are more likely to take

potentially harmful medications and to achieve stricter glycemic control. Hence, prepregnancy care may be even more effective for women with type 2 diabetes than women with type 1 diabetes.

The aim of this study was to evaluate the effectiveness of a regional prepregnancy care program on pregnancy preparation, glycemic control, and pregnancy outcomes in women with type 1 and type 2 diabetes.

## RESEARCH DESIGN AND METHODS

— We documented the potentially modifiable risk factors for adverse pregnancy outcomes in type 1 and type 2 diabetes (14) and established an interdisciplinary regional prepregnancy care team. We also performed a qualitative study to identify women's barriers to accessing prepregnancy care, namely beliefs that strict glycemic targets were unrealistic, poor relationships with health professionals, and desire for a less-medicalized pregnancy (17).

### Prepregnancy care promotion

A theoretically guided preconception leaflet (the *East Anglican Study for Improving Pregnancy Outcomes in Women with Diabetes* [EASIPOD] leaflet) with advice and telephone contacts for a prepregnancy care coordinator was mailed annually to all women aged 16–45 years identified from specialist and primary-care diabetes registers. We targeted health professionals including nurses, general practitioners, retinal-screening teams, health visitors, midwives, community pharmacists, and disseminated information via pharmacist medicine use reviews, structured education programs, local enhanced service agreements, and patient support groups.

### Prepregnancy and antenatal care delivery

Prior to pregnancy, women with type 2 diabetes were predominantly cared for by primary-care teams in community settings and women with type 1 diabetes by specialist teams in hospital settings. Referrals were accepted from specialist providers, primary care, and directly from women who received the EASIPOD leaflet. Prepregnancy care was delivered in specialist clinics without additional funding using a standardized proforma (see the online appendix, available at http://care.diabetesjournals.org/cgi/content/full/dc10-1113/DC1). The content was standardized throughout the study period (10 January 2006 through 31 September 2009) but delivered by different health care providers (diabetes physician, specialist nurse, midwife, or obstetrician). Joint clinics with diabetes and obstetric input were held in three larger units (≥30 deliveries per year), whereas smaller units provided appointments with individual nurses or physicians. The same specialist multidisciplinary health care teams provided antenatal care to women with type 1 and type 2 diabetes during pregnancy.

### Data collection

Pregnancies were registered as soon as contact with the antenatal team was established. A data collection proforma was completed for all registered pregnancies within 3 months of pregnancy completion. The project coordinator facilitated timely data collection, validation of data, and entry onto a study database.

### Maternal data

Pregnancies were described as planned if contraception was discontinued for the purposes of pregnancy. All other pregnancies were unplanned. Preconception counseling was documentary evidence of a discussion regarding the pregnancy risks associated with diabetes. Prepregnancy care was defined as a woman working in partnership with health professionals to optimize pregnancy outcome and required documented attendance at a prepregnancy clinic.

Quintiles of deprivation were derived from the postcode of residence according to the East of England Index of Multiple Deprivations (IMD) scores. Maternal A1C levels were recorded up to 6 months preconception and at up to 4–8 weekly intervals during pregnancy. They were assayed using Diabetes Control and Complications Trial–aligned methodology (normal reference range 3.6–5.8%) in accredited laboratories, with all centers participating in the national external quality-assurance program.

### Pregnancy outcome measures

Miscarriage was defined as the spontaneous ending of pregnancy before 24 weeks. We recorded termination of pregnancy for fetal malformation and described all other terminations as nontherapeutic. Congenital malformations were confirmed by postmortem results, genetic findings, or correspondence and classified according to the European Surveillance of Congenital Anomalies system. Stillbirth was fetal death after 24 weeks and neonatal death as death of a live-born infant before 28 days. A serious adverse outcome was one that resulted in major congenital malformation (included termination), stillbirth, or neonatal death.

### Statistical analyses and power calculation

Univariate analyses were performed using $\chi^2$ tests for categorical variables and *t* tests for continuous variables. For multivariate analyses, logistic regression was used. The major hypothesis of interest was whether prepregnancy care was effective in reducing adverse pregnancy outcomes, independent of potential confounding variables. Therefore, the model included maternal age, type of diabetes, diabetes duration, A1C at booking, ethnicity, socioeconomic status, BMI, parity, and smoking history as predictors in addition to whether women received prepregnancy care.

The annual birth rate for the 10 centers in the study is ~50,000, of which 200 births are complicated by pregestational diabetes. We calculated that a sample size of 580 pregnancies would give 80% power to detect a 30% reduction in the rate of serious adverse outcomes assuming 50% prepregnancy care uptake and 10% adverse outcomes.

## RESULTS

— During the 3-year study period, 686 pregnancies (median 77 per center [range 25–111]) were registered. Six pregnancies in women who moved into the region during pregnancy were excluded. For the remaining 680 pregnancies, there were no differences in the pregnancy-planning intentions (~50% planned) of women with type 1 and type 2 diabetes. Women with type 1 diabetes were more likely to have preconception counseling (54 vs. 32%; $P < 0.0001$). Overall, 181 (27%) women attended prepregnancy care, with significantly more attendees having type 1 compared with type 2 diabetes (31 vs. 20%; $P < 0.0009$). The median number of prepregnancy care visits was three (range, one to seven). Among 499 (73%) women without prepregnancy care, 157 (32%) had documented preconception counseling.

### Maternal characteristics

Women who attended prepregnancy care were more likely to be white and less likely to live in a deprived area, smoke cigarettes, and to be overweight or obese (Table 1). However, almost half of the women who attended prepregnancy care

did live in deprived areas (IMD quintiles 4–5).

### Pregnancy preparation

Attendees were more likely to have had preconception counseling ($P < 0.0001$) and to have read the EASIPOD leaflet ($P < 0.0001$). They were more likely to have 5 mg preconception folic acid (88 vs. 27%; $P < 0.0001$) and less likely to conceive on potentially harmful ACE inhibitors (1.1 vs. 4.6%; $P = 0.05$) and/or statins (0 vs. 7.6%; $P = 0.0003$). However, 10% of pregnancies occurred earlier than expected, some before folic acid (12%) was started or ACE inhibitors were stopped (1%).

Attendees presented earlier for antenatal care ($P < 0.0001$), with 70% having their first antenatal contact before 8 weeks. Their glycemic control was significantly better before pregnancy and at first contact ($P < 0.0001$), although only 53% achieved A1C ≤7%, and even fewer (17.8%) (10.9% type 1 diabetes, 32% type 2 diabetes) achieved the National Institute for Health and Clinical Excellence (NICE) glycemic control target A1C <6.1%.

### Pregnancy outcomes

Detailed pregnancy outcomes are available for 676 pregnancies (665 singleton and 11 twin), excluding four pregnancies in women who moved out of the area (Table 2). There were 2 adverse outcomes (one malformation and one stillbirth) in women with prepregnancy care and 32 adverse outcomes (23 malformations, six stillbirths, and three neonatal deaths) in women without prepregnancy care (1.3 vs. 7.8%; $P = 0.009$). Gestational age at delivery and neonatal morbidity were comparable, with equal rates of preterm delivery (50 of 150 vs. 116 of 397; $P = 0.4$), large-for-gestational-age babies (70 of 145 vs. 170 of 372; $P = 0.7$), and neonatal care admissions (50 of 147 vs. 152 of 386; $P = 0.5$) in women who did and did not attend.

### Effects of prepregnancy care in type 2 compared with type 1 diabetes

For women with type 1 diabetes, there were no differences in ethnicity or socioeconomic status of women with and without prepregnancy care (supplementary Table). As per the entire cohort, attendees had improved glycemic control and their offspring had reduced risk of adverse outcome (1.9 vs. 8.8%; $P = 0.03$).

In women with type 2 diabetes, atten-

**Table 1—*Characteristics of pregnancies in women with type 1 and type 2 diabetes according to prepregnancy care attendance***

| | PPC | No PPC | *P* value |
|---|---|---|---|
| Demographic data* | *n* = 181 | *n* = 499 | |
| Age (years) | | | |
| Median (10th–90th centile) | 33 (26–39) | 31 (22–39) | 0.002 |
| Ethnicity | | | |
| White | 166 (91.7) | 387 (77.6) | 0.0005 |
| Asian | 12 (6.6) | 90 (18.0) | |
| Other | 3 (1.7) | 22 (4.4) | |
| Social deprivation | *n* = 177 | *n* = 496 | |
| Quintile 1 (least deprived) | 30 (16.9) | 65 (13.1) | 0.01 |
| Quintile 2 | 27 (15.3) | 67 (13.5) | |
| Quintile 3 | 47 (26.6) | 91 (18.3) | |
| Quintile 4 | 34 (19.2) | 100 (20.2) | |
| Quintile 5 (most deprived) | 39 (22.0) | 173 (34.9) | |
| Weight | *n* = 176 | *n* = 451 | |
| Weight at booking (kg) | | | |
| Median (10th–90th centile) | 71.5 (56.9–99.0) | 74.5 (58.0–105.0) | 0.03 |
| BMI at booking (kg/m$^2$) | | | |
| Median (10th–90th centile) | 26.1 (21.3–36.2) | 27.9 (22.2–38.1) | 0.005 |
| Normal (BMI ≤24.9) | 73 (41.5) | 131 (29.0) | |
| Overweight (BMI 25–29.9) | 45 (25.6) | 147 (32.6) | |
| Obese (BMI ≥30) | 58 (33.0) | 173 (38.4) | |
| Diabetes status | *n* = 181 | *n* = 499 | |
| Diabetes duration (years) | | | |
| Median (10th–90th centile) | 10 (2–27) | 7 (1–22) | 0.01 |
| Maternal complications | | | |
| Retinopathy | 43 (23.8) | 91 (18.2) | 0.1 |
| Nephropathy | 5 (2.8) | 11 (2.2) | 0.9 |
| Neuropathy | 3 (1.7) | 10 (2.0) | 1.0 |
| Glycaemic control | | | |
| A1C prepregnancy (%) | | | |
| Median (10th–90th centile) | 7.2 (6.0–8.8) | 8.1 (6.1–11.7) | <0.0001 |
| A1C at first contact (%) | | | |
| Median (10th–90th centile) | 6.9 (5.8–8.8) | 7.6 (6.0–10.1) | <0.0001 |
| A1C <7.0%† | 72/135 (53.3) | 113/298 (37.9) | 0.004 |
| A1C first trimester (%) | | | |
| Median (10th–90th centile) | 6.9 (5.8–8.4) | 7.4 (6.0–9.7) | <0.0001 |
| A1C second trimester (%) | | | |
| Median (10th–90th centile) | 6.4 (5.4–7.4) | 6.5 (5.5–8.2) | 0.001 |
| A1C third trimester (%) | | | |
| Median (10th–90th centile) | 6.4 (5.5–7.5) | 6.5 (5.3–7.9) | 0.05 |
| Diabetes treatment at conception | | | |
| Diet alone | 4 (2.2) | 69 (13.8) | <0.0001 |
| Insulin | 166 (91.7) | 317 (63.5) | <0.0001 |
| Sulphonylurea | 0 (0) | 16 (3.2) | 0.03 |
| Metformin | 40 (22.1) | 124 (24.8) | 0.5 |
| Metformin alone | 12 | 107 | |
| Metformin and insulin | 28 | 17 | |
| Glitazone | 1 (0.6) | 21 (4.2) | 0.03 |
| Diabetes therapy at delivery | | | |
| Insulin | 154/154 (100) | 384/408 (94.1) | 0.004 |
| Pregnancy preparation | | | |
| Preconception counselling | 150/181 (82.9) | 157/496 (31.7) | <0.0001 |
| EASIPOD leaflet read | 68/156 (43.6) | 67/451 (14.9) | <0.0001 |
| Planned pregnancy | 162/178 (91) | 168/448 (37.5) | <0.0001 |
| Folic acid preconception | 157/178 (88.2) | 112/420 (26.7) | <0.0001 |
| Potentially harmful medications | | | |
| ACE inhibitor at conception | 2 (1.1) | 23 (4.6) | 0.05 |
| Statin therapy at conception | 0 (0) | 38 (7.6) | 0.0003 |
| Gestational age at booking (weeks) | | | |
| Median (10th–90th centile) | 6.7 (4.4–10.2) | 7.7 (5.1–14.6) | <0.0001 |

*continued*

**Table 1—*Continued***

| | PPC | No PPC | *P* value |
|---|---|---|---|
| Booked before 8/40 | 117/167 (70.0) | 240/457 (52.5) | 0.0001 |
| Smoking status at conception | | | |
| Nonsmoker | 151 (83.9) | 348 (71.4) | 0.0002 |
| Ex-smoker | 15 (8.3) | 34 (7.0) | |
| Current smoker | 14 (7.8) | 105 (21.6) | |

Data are *n* (%) unless otherwise indicated. *Six pregnancies in women who moved into the area during pregnancy are excluded as details of their preconception counseling and prepregnancy care were lacking. †The proportion of women achieving the more stringent NICE-recommended A1C target of <6.1% introduced during this study was 17.8% women with prepregnancy care (10.9% type 1 diabetes, 32% type 2 diabetes) vs. 10.4% (5.1% type 1 diabetes, 16.5% type 2 diabetes) without prepregnancy care ($P = 0.05$).

**Table 2—*Pregnancy outcomes of women with diabetes according to prepregnancy care attendance***

| | PPC | No PPC | *P* value |
|---|---|---|---|
| Pregnancy outcome[1] | *n* = 181 | *n* = 495 | |
| Miscarriage | 28 (15.5) | 71 (14.3) | 0.9 |
| Termination of pregnancy | 1 | 25 | |
| Termination of pregnancy fetal abnormality | 0 | 9 | 0.2 |
| Termination of pregnancy non-diabetes associated* | 1 | 16 | |
| Delivery[2] | *n* = 152 | *n* = 399 | |
| Gestational age at delivery (weeks) | | | |
| Median (10th–90th centile) | 37.6 (34.6–38.9) | 37.7 (34.7–39.0) | 0.3 |
| Type of delivery | | | |
| SVD including instrumental | 53 (34.9) | 177 (44.4) | 0.05 |
| LSCS | 99 (65.1) | 222 (55.6) | |
| Planned LSCS | 49 (32.2) | 101 (25.3) | 0.6 |
| Emergency LSCS | 50 (32.9) | 121 (30.3) | |
| Twins | 5 | 6 | |
| Perinatal morbidity | | | |
| Prematurity[3] | *n* = 150 | *n* = 397 | |
| <37 weeks gestation | 50 (33.3) | 116 (29.2) | 0.4 |
| <34 weeks gestation | 9 (6.0) | 27 (6.8) | 0.9 |
| Infant birth weight centiles[4] | *n* = 145 | *n* = 372 | |
| Large for gestational age | 70 (48.3) | 170 (45.7) | 0.7 |
| Extremely large for gestational age | 50 (34.4) | 114 (30.6) | 0.5 |
| Small for gestational age | 7 (4.8) | 32 (8.6) | 0.2 |
| Neonatal care[5] | *n* = 147 | *n* = 386 | 0.5 |
| Home birth | 0 (0) | 1 (0.3) | |
| Postnatal ward | 74 (48.3) | 183 (47.4) | |
| Level 1 | 23 (15.6) | 50 (13.0) | |
| Level 2 | 37 (25.2) | 123 (31.9) | |
| Level 3 | 13 (8.8) | 29 (7.5) | |
| Pregnancy outcomes[6] | *n* = 152 | *n* = 408 | |
| Malformation | 1 (0.7) | 23 (5.6) | 0.02 |
| Stillbirth | 1 (0.7) | 6 (1.5) | 0.7 |
| Neonatal death | 0 (0) | 3 (0.7) | 0.7 |
| Perinatal mortality | 1 (0.7) | 9 (2.2) | 0.4 |
| Serious adverse outcome (malformation with or without termination of preganancy, stillbirth, or neonatal death) | 2 (1.3) | 32 (7.8) | 0.009 |

Data are *n* (%) unless otherwise indicated. [1]All pregnancies excluding four pregnancies in women who moved out of the area during pregnancy (*n* = 676). *We are confident that all pregnancy termination data in women with prepregnancy care are included but cannot exclude an even higher number of nontherapeutic terminations in women without prepregnancy care. [2]All pregnancies after 20 weeks' gestation excluding 99 spontaneous miscarriages and 26 terminations (*n* = 551). [3]All pregnancies excluding four infants for whom data on gestational age at delivery were missing (*n* = 547). [4]All pregnancies resulting in live singleton births excluding 18 for whom birth weight centiles were missing (*n* = 517). [5]All pregnancies resulting in live singleton births excluding one infant in whom care level was not recorded (*n* = 533). [6]All pregnancies after 20 weeks' gestation (551) and 9 terminations for congenital malformation (*n* = 560).

dance was poor (20%). However, despite their better glycemic control (compared with women with type 1 diabetes), prepregnancy care attendees still achieved significantly better glycemic control both before pregnancy ($P < 0.0001$) and throughout the first two trimesters ($P = 0.007$ and $P = 0.03$). There were no malformations or adverse outcomes in the offspring of attendees compared with 10 malformations (5.6%) and 12 adverse outcomes (6.8%) in the offspring of women without prepregnancy care, but with small numbers these differences were not significant.

### Predictors of serious adverse pregnancy outcome

In contrast to the general maternity population, maternal age, parity, obesity, ethnicity, and socioeconomic deprivation were not independently associated with adverse outcome (Table 3). The independent predictors were glycemic control at booking (odds ratio 1.46 [95% CI 1.16–1.85]; $P = 0.001$ per 1% A1C increase) and lack of prepregnancy care (0.2 [0.05–0.89]; $P = 0.03$). Diabetes duration and type 1 diabetes approached, but did not reach, significance ($P = 0.06$ and $P = 0.07$).

### Pregnancy outcomes during 2006–2009 compared with during 1999–2004

Notable differences were the increased proportion of pregnancies complicated by type 2 diabetes (40 vs. 27%; $P < 0.0001$), increased preconception counseling and folic acid supplementation particularly in type 1 diabetes, and increased metformin use in type 2 diabetes (Table 4). Despite fewer malformations (4.3 vs. 7.3%; $P = 0.04$) during the prepregnancy care program, overall differences in perinatal mortality (1.8 vs. 3.7%; $P = 0.07$) and adverse outcome (6.0 vs. 9.2%; $P = 0.07$) were not significant. Rates of adverse outcomes were unchanged (6.5%) in type 1 diabetes. In type 2 diabetes, there were reductions both in adverse outcomes (5.3 vs. 16.4%; $P = 0.0008$) and in malformations (4.5 vs. 12.3%; $P = 0.009$).

**CONCLUSIONS** — Here, we report the development and evaluation of a regional prepregnancy care program, implemented in routine care, which was associated with improved glycemic control and reduced risk of adverse pregnancy outcome in pregnancies complicated by both type 1 and type 2 diabetes. Approximately half the women

**Table 3—*Independent predictors of serious adverse pregnancy outcome (major congenital malformation, stillbirth, or neonatal death) in pregnancies complicated by type 1 and type 2 diabetes***

| Variable | Odds ratio (95% CI) | *P* value |
|---|---|---|
| Age (years)[1] | 1.01 (0.93–1.09) | 0.9 |
| Type 1 diabetes[2] | 3.41 (0.89–13.0) | 0.07 |
| Duration of diabetes (years)[3] | 1.06 (1.00–1.12) | 0.06 |
| A1C at booking[4] | 1.46 (1.16–1.85) | 0.001 |
| European ethnicity | 0.36 (0.09–1.46) | 0.2 |
| Social disadvantage | 1.00 (0.76–1.32) | 1.0 |
| Prepregnancy care[5] | 0.20 (0.05–0.89) | 0.03 |
| BMI | 0.95 (0.88–1.03) | 0.2 |
| Parity[6] | 1.77 (0.75–4.14) | 0.2 |
| Smoking | 1.41 (0.93–2.15) | 0.1 |

[1]Increase in risk for every extra year of age. [2]Increase in risk for women with type 1 diabetes as opposed to type 2 diabetes. [3]Increase in risk for every extra year of diabetes duration. [4]Increase in risk for every extra 1% of A1C. [5]Decrease in risk for women who attend a prepregnancy care clinic as compared with women who did not attend prepregnancy care. [6]Increase in risk for multiparous women as opposed to primiparous women.

had planned pregnancies and documented preconception counseling, suggesting fairly widespread health care interaction. However, less than a third benefited from prepregnancy care, suggesting failings of conventional models of engagement. This emphasizes the need to rethink how preconception counseling is delivered both at a population level and to women with preexisting medical conditions. In the U.K., preconception services are fragmented and variable, comparing poorly to other European countries, where effective prepregnancy care has been successfully implemented (2).

In contrast to other U.K. and U.S. studies, we found no association between social disadvantage and prepregnancy care attendance in women with type 1 diabetes (18,19). Ethnicity and living in a deprived area were barriers to access only in women with type 2 diabetes. Our qualitative study suggested that unrealistic glycemic control targets, poor communication, and "too much emphasis on all the bad things that could happen" are important barriers to engagement both for women with type 1 and type 2 diabetes (17), further emphasizing the need to deliver prepregnancy care in a positive, motivating, and supportive manner.

In this cohort, neither age, parity, ethnicity, social disadvantage, nor obesity predicted adverse pregnancy outcome. This could be because the study was underpowered to examine these effects or because glycemic control and pregnancy preparation are the strongest influences of adverse outcome in pregnancies complicated by type 1 and type 2 diabetes.

## Challenges in type 1 diabetes

Even motivated attendees struggled to achieve optimal preconception glycemic control. Among women with type 1 diabetes, only 10% with prepregnancy care and 5% without prepregnancy care achieved A1C levels <6.1% compared

**Table 4—*Indicators of pregnancy preparation and pregnancy outcomes during the 2006–2009 regional prepregnancy care program compared with during 1999–2004***

| | 1999–2004 | 2006–2009 | | *P* value |
|---|---|---|---|---|
| Type of diabetes[1] | | | | |
| Type 1 | 443 | 408 | | <0.0001 |
| Type 2 | 162 (26.8) | 274 (40.2) | | |
| Pregnancy loss <20/40 | 60/613 (9.8) | 125/686 (18.5) | | <0.0001 |
| Preconception counselling[2] | 200/535 (32.5) | 245/562 (43.6) | | 0.04 |
| Type 1 diabetes | 153/389 (40.5) | 178/337 (52.8) | | |
| Type 2 diabetes | 42/146 (28.7) | 67/225 (29.8) | | |
| Folic acid preconception | 174/535 (32.5) | 229/562 (40.7) | | 0.006 |
| Type 1 diabetes | 142/389 (36.4) | 155/337 (46.0) | | |
| Type 2 diabetes | 32/146 (21.9) | 74/225 (32.9) | | |
| Metformin | | | | |
| Type 2 diabetes | 51/146 (35.2) | 123/225 (54.7) | | 0.0003 |
| Pregnancy outcome[2] | | | | |
| Congenital malformation | 39/535 (7.3) | 24/562 (4.3) | | 0.04 |
| Type 1 | 17/389 (4.4) | 14/337 (4.2) | 1.0 | ($P = 0.05$ for interaction) |
| Type 2 | 18/146 (12.3) | 10/225 (4.4) | 0.009 | |
| Perinatal mortality | 20/535 (3.7) | 10/562 (1.8) | | 0.07 |
| Type 1 | 11/389 (2.8) | 8/337 (2.4) | 0.9 | ($P = 0.03$ for interaction) |
| Type 2 | 9/146 (6.2) | 2/225 (0.9) | 0.009 | |
| Serious adverse outcome | 49/535 (9.2) | 34/562 (6.0) | | 0.07 |
| Type 1 | 25/389 (6.4) | 22/337 (6.5) | 0.9 | ($P = 0.007$ interaction) |
| Type 2 | 24/146 (16.4) | 12/225 (5.3) | 0.0008 | |

Data in parentheses are percentages. [1]Includes all registered pregnancies in women with type 1 and type 2 diabetes during the 2 study periods. [2]For direct comparison with the 1999–2004 study, we have excluded all pregnancies that resulted in miscarriage at <20 weeks' gestation and all terminations for indications other than congenital malformation.

with 32 and 16.5%, respectively, of women with type 2 diabetes. It should be noted that only a minority of women (9.4%) used insulin pump therapy before or during pregnancy and that continuous glucose monitoring was not routinely available. Consequently, despite improved pregnancy preparation in women with type 1 diabetes, their glycemic control and risk of adverse pregnancy outcome were disappointingly unchanged over the two study periods. A nationwide Swedish study of over 5,000 pregnancies also concluded that type 1 diabetes is still associated with considerably increased adverse obstetric and perinatal outcomes, again highlighting a lack of progress over the past decade (20).

There is emerging evidence supporting the benefits of continuous glucose monitoring both before and during pregnancy (21,22). Large multicenter studies are now needed to evaluate the effects and cost effectiveness of continuous glucose monitoring on maternal glycemic control and pregnancy outcomes. Recent innovations, including sensor-augmented insulin pumps and closed-loop technologies, may also help more women with type 1 diabetes to achieve near normoglycaemia (23,24).

### Improvements in type 2 diabetes

This study has highlighted encouraging improvements for pregnant women with type 2 diabetes, with significant reductions in rates of adverse pregnancy outcomes, over the past decade. This may represent a milder glycemic disturbance (25) and/or improvements in the management of type 2 diabetes. Importantly, it suggests that organized efforts to improve preconception glycemic control can have a beneficial effect for women with type 2 diabetes despite their obstetric risk factors.

### Strengths and limitations

We carefully documented the maternal demographics and obstetric and diabetes risk factors in a large, contemporary cohort of women with diabetes. The program was implemented across 10 regional maternity units, reducing selection bias from specialist centers of excellence. A major strength is the inclusion of women with both type 1 and type 2 diabetes and the detailed content and delivery format for prepregnancy care, which previous studies lack. Furthermore, we evaluated the role of prepregnancy care in addition to preconception counseling and included details of preconception medication use and of pregnancy terminations, documenting the prevalence of terminations (both therapeutic and nontherapeutic) in women with diabetes.

A limitation is that it is not a randomized trial, and differences in the motivation of women who do and do not attend prepregnancy care are likely. However, a randomized trial is neither ethical nor clinically feasible. We therefore performed a robust observational cohort study, documenting and correcting for potential confounding factors, including age, parity, obesity, ethnicity, and socioeconomic status. We also have a historical cohort with details of pregnancy outcomes in the same centers before and during the program (14).

Prepregnancy care has failed to keep pace with recent educational and technological developments. Structured programs with evidence-based curriculums, standardized delivery by trained health professionals, and access to continuous glucose monitoring and insulin pump therapy are urgently required. For women with diabetes, prepregnancy care is as essential as antenatal care and needs to be resourced, quality assured, and researched to a similar standard. More work is needed to increase attendance, overcome the socioeconomic and ethnic barriers to access in type 2 diabetes, and to further improve glycemic control in type 1 diabetes.

**Acknowledgments**— This work was supported by Diabetes UK Project Grant BDA 06/0003197. H.R.M. is funded by a National Institute for Health Research (NIHR) Research Fellowship (PDF/08/01/036).

No potential conflicts of interest relevant to this article were reported.

H.R.M., J.M.R., and R.C.T. designed the study, interpreted the data, and wrote the manuscript. J.M.R., D.S., S.T., E.G., N.J.M., S.C.S., S.K., and B.L. provided clinical care and supervised data collection. All authors reviewed/edited the manuscript. T.C.S. developed the EASIPOD preconception leaflet available at http://www.diabetes.org.uk/professionals/shared_practice/care_topics/pregnancy/easipod_East_Anglian_Study_for_Improving_Pregnancy_outcomes_in_women_with_diabetes/.

Parts of this manuscript were presented in abstract form at the Diabetes UK Annual Professional Conference, 4 March 2010 and the European Association for the Study of Diabetes (EASD) Diabetes Pregnancy Study Group, 26 September 2009.

We thank the regional diabetes clinicians, obstetricians, nurses, and midwives for accurate data collection and excellent clinical care; Sian Evans (Eastern Region Public Health Observatory) for maternal deprivation scores; and Peter Campbell (Sanger Institute, Cambridge, U.K.) for statistical input.

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