The National Pregnancy in Diabetes (NPID) audit: challenges and opportunities for improving pregnancy outcomes

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What’s new?

- The 2016 National Pregnancy in Diabetes audit demonstrates little change in pregnancy preparation or outcomes and substantial clinic-to-clinic variations in care.
- Reproductive health needs to be as integrated into the diabetes care plans of women with diabetes as retinal screening or annual reviews.
- Awareness raising about pre-pregnancy care could be improved in primary care settings using mobile technology, information prescriptions and electronic templates.
- As device usability improves, closed-loop and automated insulin delivery systems may help to minimize the impact of clinic-to-clinic variations.

Abstract

Our aim was to review the data from the National Pregnancy in Diabetes (NPID) audit, and to identify the challenges and opportunities for improving pregnancy outcomes in women with diabetes. We reviewed three years of NPID data and relevant diabetes and obstetric literature, and found that there has been little change in pregnancy preparation or outcomes over the past 3 years, with substantial clinic-to-clinic variations in care. Women with Type 2 diabetes remain less likely to take 5 mg preconception folic acid (22.8% vs. 41.8%; \( P < 0.05 \)), and more likely to take potentially harmful medications (statin and/or ACE inhibitor 13.0% vs. 1.8%; \( P < 0.05 \)) than women with Type 1 diabetes. However, women with Type 1 diabetes are less likely to achieve the recommended glucose control target of HbA1c < 48 mmol/mol (6.5%) (14.9% vs. 38.1%; \( P < 0.05 \)). The following opportunities for improvement were identified. First, the need to integrate reproductive health into the diabetes care plans of all women with diabetes aged 15–50 years. Second, to develop more innovative approaches to improve uptake of pre-pregnancy care in women with Type 2 diabetes in primary care.
settings. Third, to integrate insulin pump, continuous glucose monitoring and automated insulin delivery technologies into the pre-pregnancy and antenatal care of women with Type 1 diabetes. Fourth, to improve postnatal care with personalized approaches targeting women with previous pregnancy loss, congenital anomaly and perinatal mortality. A nationwide commitment to delivering integrated reproductive and diabetes healthcare interventions is needed to improve the health outcomes of women with diabetes.

**<H1>Background**

The National Pregnancy in Diabetes (NPID) audit was developed from existing regional diabetes in pregnancy networks and paper-based audits, in response to the Confidential Enquiry into Maternal and Child Health of 2002–2003, which quantified the potentially preventable poor pregnancy outcomes in women with diabetes [1–3].

In consultation with key stakeholders from diabetes, obstetrics, public health, midwifery and nursing services, and including women with diabetes, the following three questions were identified. First, were women with diabetes adequately prepared for pregnancy? Second, were appropriate steps taken to minimize adverse outcomes to the mother? Third, were appropriate steps taken to minimize adverse outcomes to the baby? These questions were closely aligned with the standards set out in the National Institute for Health and Clinical Excellence (NICE) clinical guidelines [4].

A two-stage ‘proof of concept’ validation study was undertaken. Retrospective data including consecutive pregnancies for 1381 women from three existing regional networks were used to identify the minimum standard dataset to answer the audit questions [1]. These were refined, tested for transferability and feasibility of collection across new maternity units who had not previously participated in regional audits [2]. With advances in technology, paper-based data forms were replaced by online data-collection systems. Prospective data using a standard
dataset that met the NHS Digital data standards were collected. Improved IT infrastructures allowed data from the National Diabetes Audit (NDA), Hospital Episode Statistics (HES), Patient Episode database for Wales (PEDW) and existing congenital anomaly registers to be incorporated, reducing the burden of local data collection.

The NPID audit was launched as a part of the NDA portfolio with data collection from June 2013 across England, Wales and the Isle of Man. Each annual cycle of data is reported in October–November of the following year, to ensure the data are contemporaneous and relevant to current clinical care.

The purpose is to provide the metrics needed to benchmark care and outcomes in relation to NICE guidelines at a local, regional and national level. This also allows individual units, and regions to measure the impact of differences or changes in practice. All maternity units that are delivering women with pre-gestational diabetes are expected to contribute with increasing participation of women (1697 to 3297) and of units (128 to 172) between 2013 and 2016. As participation in the audit approaches full inclusion, we can better understand both the opportunities and the challenges for improving pregnancy outcomes.

**The changing demography of diabetes in pregnancy**

There has been a significant increase in the proportion of pregnant women with Type 2 diabetes from 27% in 2002–2003 to 50% currently [5]. During 2016 there were, for the first time, more babies born to women with Type 2 diabetes than to women with Type 1 diabetes (Table 1). Some metropolitan centres now have > 70% of diabetes pregnancies in women with Type 2 diabetes. Nearly half of women with Type 2 diabetes are of Asian, Afro-Caribbean or mixed ethnicity, meaning that 90% of Asian and 70% of Afro-Caribbean diabetes pregnancies are in women with Type 2 diabetes [5]. As has been previously
reported, women with Type 2 diabetes are more likely to come from areas of social
deprivation, be older, have higher BMI and have shorter duration of diabetes [6].

This means that an increasing proportion of women have their routine diabetes care delivered
outside specialist settings, where awareness of the specific issues of safe effective
contraception and the risks of pregnancy associated with diabetes is limited. This leads to
misconceptions and low levels of awareness among women of reproductive years with
inadequate contraception to avoid unintended pregnancy and limited specific information to
support optimal pregnancy preparation. Structured education programmes for Type 2 diabetes
typically focus on older age groups, and do not routinely include contraception, the particular
challenges of finding appropriate contraception for older women with higher BMI, and often
additional cardiovascular risk factors, and the importance of pregnancy preparation. There
may also be additional cultural and ethnic barriers to accessing contraception, that need to be
overcome for women with Type 2 diabetes.

**Preparation for pregnancy**

Pregnancy is challenging for women with diabetes, as hyperglycaemia at any stage is
associated with increased risk of complications for both mother and baby [7]. Early
pregnancy (the first 6–7 weeks) is particularly crucial, as this is when organogenesis occurs.
Hyperglycaemia in early pregnancy, lack of folic acid supplementation and taking potentially
harmful diabetes medications, may all contribute to increased rates of congenital
malformation [8]. In addition, before 8 weeks, women may not yet be aware that they are
pregnant, and hence do not act to ameliorate the risks. Thus, the NICE guidelines recommend
that all women with diabetes need either safe effective contraception to avoid an unintended
pregnancy, or pre-pregnancy care to reduce diabetes-related risk factors before conception
[4].
Three key measures of pre-pregnancy care are captured in the NPID audit. These are use of 5 mg folic acid, use of potentially harmful medications (statins, ACE inhibitors and glucose-lowering medication other than insulin or metformin) before pregnancy, and maternal HbA1c level, targeting < 48 mmol/mol (6.5%) at the first antenatal visit.

The benefits of pre-pregnancy care are well established, with fewer adverse maternal–fetal outcomes among women who are prepared for pregnancy compared with those who are not [9–12]. However, less than half of women with diabetes attend pre-pregnancy care [5]. Women with Type 1 diabetes are more likely to take 5 mg folic acid before pregnancy (41.8% vs. 22.8%) (Fig. 1) and less likely to take potentially harmful medications (statin and/or ACE inhibitor 1.8% vs. 13.0%), than women with Type 2 diabetes [5].

The glycaemic control target of HbA1c < 48 mmol/mol (6.5%) is achieved by only a minority of women with diabetes. Women with Type 2 diabetes are more than twice as likely to achieve this target (38.1% vs. 14.9%) than women with Type 1 diabetes. Women with greater levels of social deprivation are less likely to achieve this target. Worryingly, 12.5% of women with Type 1 and 7.4% of women with Type 2 diabetes have HbA1c levels > 86 mmol/mol, carrying an ~ 10% risk of serious adverse pregnancy outcome [5].

The implications of these findings are that, although women with Type 2 diabetes have better glucose control, their behaviours around folic acid supplementation, use of potentially harmful medications and delayed presentation for antenatal care suggests that they are often poorly informed about the risks of diabetes in pregnancy, and what they can do to prepare for pregnancy.
<H1>Glucose control</H1>

Data from successive NPID audits highlight the gap between the NICE glucose control targets, and what is achieved in routine antenatal care. Women who achieve the recommended HbA1c targets in early pregnancy are older, with shorter duration of diabetes and are less likely to live in a deprived region [5]. More women using insulin pump therapy achieve target HbA1c levels in early pregnancy compared to women using multiple daily injection (MDI) (20% vs. 13%; P < 0.05). Data, collected over the 3-year period 2014–2016 highlight the important role of potentially modifiable clinical factors [13]. Data from individual units show striking levels of clinic-to-clinic variation in the proportion of women with diabetes achieving target HbA1c levels, both in Type 1 and Type 2 diabetes. This clinic-to-clinic variation persists, so that even in late pregnancy (after 24 weeks gestation) it ranges from 0% to 82% in Type 1 diabetes and from 43% to 100% in Type 2 diabetes (Fig. 2). This contributes to the one in two babies at risk of complications related to maternal hyperglycaemia. During 2016, the rates of large for gestational age infants, preterm delivery, and babies admitted for neonatal care remained high, especially in babies of mothers with Type 1 diabetes (47% large for gestational age, 43% preterm and 40% admitted for neonatal care).

<H1>Risks of recurrent adverse outcomes in women with diabetes</H1>

Audits such as NPID allow us to quantify, and monitor over time, the high risk of adverse pregnancy outcome associated with diabetes [2,6,14]. However, these cross-sectional data provide aggregate estimates for all pregnancies, and little is known about how the risks may change for an individual woman with each subsequent pregnancy. Most women experience more than one pregnancy over their reproductive years. Longitudinal studies suggest that, for

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women without diabetes, the risk of a recurrent miscarriage, stillbirth and congenital anomaly are approximately doubled in a second pregnancy, if experienced in their first pregnancy [15–17].

Tennant et al. [18] reported on the first and second pregnancies of 220 women with diabetes in northeast England (89% Type 1), aiming to quantify the risk of recurrence of adverse pregnancy outcome. In this study, 30.5% of first pregnancies had a serious adverse outcome, defined as miscarriage, congenital anomaly (6.4%), stillbirth or infant death. Although, the overall risk was much lower in second pregnancies (16.8%), the risk of a second adverse outcome remained more than doubled among women with an adverse outcome in the first pregnancy. This increased risk was confounded by non-modifiable risk factors such as maternal ethnicity, but there was a strong association with increased peri-conception HbA$_1c$ level.

Tennant et al. [18] also explored whether preparation for pregnancy changed between the first and second pregnancies. Similar to NPID findings, pregnancy preparation was suboptimal, with less than a quarter of women achieving HbA$_1c$ < 53 mmol/mol (7%) and 27% taking folic acid before their first pregnancy. Despite some improvement in preparation for the second pregnancy, in general, women who were better or poorly prepared for their first pregnancy, were also better or poorly prepared for their second pregnancy [18]. Hence, women with a previous adverse outcome were no more likely to prepare for the second pregnancy. Importantly, the median inter-pregnancy interval for these women was only 12 months, suggesting a relatively short window of opportunity to optimize preparation for the next pregnancy. Providing enough information to support these women without overwhelming them with negativity can be particularly challenging; ‘She didn’t like the horror stories as she calls them; all the bad things that could happen’ [19].
<H1>How to improve preconception care</H1>

Pre-pregnancy care aims to identify and modify biomedical, behavioural and social risks to women's reproductive health and pregnancy outcomes through prevention of unintended pregnancy and appropriate risk management [20]. NICE and other international guidelines recommend that pre-pregnancy care be incorporated into routine diabetes consultations from adolescence onwards [4,21].

Interventions to enhance the uptake of pre-pregnancy care include education, information leaflets and clinic proformas, targeting both healthcare professionals and women with diabetes [9,10]. Most studies are implementing and evaluating the interventions concurrently, but lack longer term follow-up when the processes have ‘bedded-in’. The interventions target all women aged 16–50 years, with limited impact (between 27% and 33%) on pre-pregnancy care attendance. Therefore, although we have a good understanding of what care is needed, and when this should be delivered, the challenge remains about how best to improve uptake of pre-pregnancy care by those for whom it is relevant. A consistent finding is that women with Type 2 diabetes are less likely to attend pre-pregnancy care than women with Type 1 diabetes [6,10,13,22]. This is particularly important as women with Type 2 diabetes represent an increasing proportion of those with pre-gestational diabetes and of those who are most likely to enter pregnancy unprepared [5].

Qualitative studies have sought to explore the pre-pregnancy care experiences of women with diabetes and of healthcare professionals [19,23,24]. A synthesis of these data has highlighted a dissonance in the approach to, understanding of and communication about pre-pregnancy care between the women and professionals [25]. Professionals focus on pregnancy and preconception care, rather than talking about sexual activity and use of effective methods of contraception. The average age of first sexual intercourse is 16 years, with a 13–14-year
interval (and a lot of sexual activity) before the average age of a first pregnancy. Likewise, the average woman has 2.3 children, and so information that is relevant to women’s reproductive intentions need to be relevant, personalized, updated and continued.

Interactions between professionals and women with diabetes are weighted toward other agendas (annual reviews, retinal screening, etc.) and often do not elicit the women’s use of contraception or reproductive intentions [25]. Currently in the UK, women with Type 2 diabetes are specifically disadvantaged, as pre-pregnancy care is not a remunerable indicator for primary care providers in the quality outcomes framework (QOF), which focuses on control of lipids, blood pressure and HbA1c. Similarly, pre-pregnancy care is not an important focus on the curricula of structured education programmes for Type 2 diabetes.

Some areas within the UK have reconfigured their diabetes services with the explicit intention of bringing specialist healthcare professionals with an emphasis on pre-pregnancy care into community settings [26]. However, in general, pre-pregnancy care is fragmented, therefore concerted and innovative approaches are needed to integrate it into the routine care of women with diabetes [27]. Alternative strategies to improve women’s awareness of how to reduce the risks of unplanned pregnancy are emerging. Recent studies have focused on the use of multimedia technologies, namely interactive CD-ROM and DVDs [28–30]. Although data on the impact of these initiatives are limited, they are associated with an increase in the perceived benefits and attitudes to contraceptive use, as well as improvements in knowledge and increased intention to initiate a discussion about pre-pregnancy care [28–30].

Mobile health (mHealth) technology is another strategy to enhance the uptake of pre-pregnancy care. It has been estimated that 90% of the world’s population has access to mobile networks, with smartphones, which have the capacity to run applications (apps), accounting for a substantial proportion of mobile devices. These advances have resulted in a
proliferation of healthcare education, decision-making support, and self-care monitoring apps [31]. The potential reach of this technology has important implications for raising awareness of and engagement with pre-pregnancy care. Evaluation of an app designed for pregnant women with diabetes reported that 75% of women had downloaded a locally developed app, with almost half having actively engaged with it before pregnancy [32]. Therefore, seizing on this shift towards greater use of mobile technology, awareness raising about pre-pregnancy care could be improved. A robust programme of awareness raising and education, for women with diabetes and healthcare professionals, is needed for the systematic integration of reproductive healthcare into the routine diabetes care of women with diabetes.

<H1>Improving glucose control in Type 1 diabetes pregnancy</H1>

Glucose monitoring is the cornerstone of diabetes self-management. For pregnant women using insulin, self-management requires painstaking attention to glucose monitoring, with at least 7–10 daily capillary glucose tests (before meals, 1 and/or 2 h post meals, before driving, and before bed), and meticulous attention to adjusting insulin doses based on glucose levels, dietary intake and physical activity [4]. In addition, the physiological changes of pregnancy mean that insulin requirements are constantly changing, with most women needing higher doses initially, followed by insulin dose reduction in the late first trimester (typically 10–16 weeks), and then a progressive increase from 20–24 weeks onwards [33]. As pregnancy advances, there is diminished skeletal muscle uptake of glucose, leading to maternal hyperglycaemia, and providing more glucose to the growing fetus [34]. The complexity of insulin dose adjustment is further complicated by the pharmacological limitations of insulin. There is a slower time to peak plasma concentration of insulin and more day-to-day variability in insulin pharmacokinetics in late pregnancy [34,35]. While fast-acting insulin analogues (Aspart, Humalog) should be injected at least 15 min before eating, the considerably slower absorption in late pregnancy means that even earlier pre-meal boluses
are advised. For many pregnant women, this means injecting 30–60 min before eating in late gestation. In clinical practice, continuous glucose monitoring (CGM) provides more confidence for earlier pre-meal bolusing and immediate feedback on the success, or not, of insulin dosing decisions.

In a randomized controlled trial across 31 international centres, women using CGM had only slightly lower HbA$_{1c}$ levels [2 mmol/mol (0.2%)] compared with the capillary glucose monitoring group, but spent an additional 100 min per day with glucose levels in the target range [36]. This was achieved without increasing hypoglycaemia or insulin dose. The findings were consistent across clinics and comparable in insulin pump and MDI users.

Taken together, these data suggest that more information about their glucose levels helped women with their daily insulin dosing and diabetes self-management decisions. Importantly, even these modest improvements in maternal glucose control, were associated with a substantial reduction in neonatal complications. Infants of mothers using CGM had significantly lower rates of large for gestational age, fewer neonatal intensive care unit (NICU) admissions, fewer episodes of neonatal hypoglycaemia and a 1-day shorter length of hospital stay [36]. The number of women needed to treat with CGM to prevent a neonatal complication was six for large for gestational age and neonatal hypoglycaemia and eight for NICU admission. Women started CGM at 12 ± 2 weeks’ gestation, meaning that continuous use until delivery required ~ 6–7 months of CGM. Given the high NHS costs of NICU admission, particularly among preterm infants, and the shorter duration of in-hospital care, the cost of CGM use during pregnancy (~ £210/month for the sensors used in our trial) will, at least in part, be offset by the potential neonatal healthcare savings. The next generation real-time CGM sensors are expected to have a longer lifespan (7–10 days), which will further reduce the costs. It is not known whether the more affordable Freestyle Libre system with a
14-day lifespan, but without alarms or alerts to warn of impending out of range glucose levels, will also be effective.

In the setting of this randomized controlled trial, with motivated participants and clinics, the level of glucose control achieved was still suboptimal. Women in the standard care group using pumps or MDI achieved on average only 60% time-in-target (14.4 h/day) by 34 weeks’ gestation. The CGM group using MDI achieved the highest overall time-in-target (69% or 16.6 h/day), while the CGM group using insulin pump therapy spent 66% time-in-target (15.8 h/day), suggesting that optimal glucose control remains elusive even with today’s most advanced diabetes technology. The time spent with hypoglycaemia and rates of maternal hypoglycaemia were very low, suggesting that modern insulin analogues have been very helpful for minimizing hypoglycaemia, but postprandial hyperglycaemia remains the major obstacle to optimal glucose control. Further analysis of maternal dietary intake may help us understand if there are particular dietary approaches that can help to minimize post-meal hyperglycaemia.

Although not yet routinely available, closed-loop systems linking CGM with insulin delivery, offer the potential for glucose responsive, automated insulin delivery (Fig. 3). Although pre-meal boluses are still required, because of the longer insulin absorption time, hybrid closed-loop systems will adapt basal-insulin delivery according to post-meal glucose levels. Experiences from running an overnight study of closed-loop in pregnancy suggested that women were more confident giving larger insulin doses, particularly before their evening meal with the knowledge that closed-loop would minimize the risk of nocturnal hypoglycaemia by suspending insulin delivery if glucose levels were low or approaching low levels [37,38]. Many women, including those without clear biomedical benefit, describe feeling better and ‘more normal’ on wakening up in the morning, with an in-target glucose level [38]. Importantly, as for CGM, there was no difference in the treatment effect of closed-
loop, between women using insulin pumps and MDI at enrolment. Larger randomized trials of longer duration and in diverse populations of pregnant women are needed to evaluate whether automated insulin delivery systems can improve glucose control and neonatal health outcomes. Given the pharmacokinetic limitations of currently available insulin analogues and the issues associated with subcutaneous insulin delivery, closed-loop systems will be unable to achieve 90–100% time-in-target during pregnancy. However, closed-loop systems provide the best potential option for consistently achieving 70–80% time in target for a broad range of pregnant women. As device usability improves, closed-loop systems may help to minimize the impact of social disadvantage and clinic-to-clinic variations, providing personalized glucose-responsive insulin delivery, during pregnancy and delivery, when it matters most for mothers and their babies.

**Interpregnancy care**

There is scope for improving the high rate of recurrence of adverse outcome by improving the transition between postnatal support and discussion, and preparation for a further pregnancy. In recent years, there has been growing awareness of the bereavement process following miscarriage and stillbirth. Qualitative research has illuminated parents’ experiences and highlighted the importance of interactions with healthcare professionals [39]. However, evidence to support specific interventions is sparse and generally of poor quality. This partly reflects the difficulty of conducting trials or other rigorous evaluations in this sensitive area [40]. Good practice guidance for health professionals has been developed by Sands, the stillbirth and neonatal charity [41]. This emphasizes sensitive and informed postnatal follow up appointments and training for healthcare professionals in supporting grieving parents. Another area which has been highlighted is the need for additional support in subsequent pregnancies [42].
One area, which remains controversial, and is particularly pertinent to women with diabetes, is the timing of any subsequent pregnancy. In the past, it was often considered that after a pregnancy loss the best remedy was a rapid ‘replacement’ pregnancy. More recently, medical advice has suggested a delay for physical and emotional recovery, with WHO recommending a delay of at least 6 months after a miscarriage. However, a recent meta-analysis concluded that there was no evidence to support such a delay [43]. It is appreciated that a personalized approach is needed. Nevertheless, studies show that most women who experience a pregnancy loss will become pregnant again, many within 12 months [44]. Parents may seek information from health professionals about the optimal timing of a subsequent pregnancy, but can receive conflicting advice. Qualitative research with parents shows that many consider a further pregnancy very quickly, sometimes within days of a loss, although decisions to proceed may vary. One study found that fathers may be more reluctant than mothers to embark on a further pregnancy [42]. Although the decision about whether and when to proceed with a further pregnancy is a personal one, parents require evidence-based information about risks of recurrence and how to minimize those risks.

No previous studies in this area have a specific focus on the experience of women with diabetes. Furthermore, NICE guidance for the management of diabetes in pregnancy did not consider care after an adverse pregnancy outcome [4]. Given the strong association of adverse outcomes with modifiable factors such as glycaemic control and high-dose folate, there is a clear need for care in the postnatal period to co-ordinate with postnatal contraception and/or support for preparation for pregnancy [45]. Skilful communication is needed to achieve this sensitively and to support parents to come to their own decisions.

Suboptimal glycaemic control is a key factor driving the excess risk of fetal loss and congenital anomalies, and therefore in theory, interpregnancy improvements in glycaemic
control, and attention to optimizing other risk factors, could help to reduce risks in subsequent pregnancies.

**Developing an approach to improving outcomes**

The increasing participation in NPID allows unit-by-unit comparison in key pregnancy preparation and outcome measures. This, coupled with accurate demographic data, offers the opportunity to develop networks locally and nationally. Some of these will involve access to better and more consistent pre- and post-pregnancy information in primary care, through social media, or through incorporation into education programmes for women with diabetes. Others will require engagement with local communities, clear referral pathways to specialist teams before pregnancy, and leadership and coordination across public health, primary care, maternity and diabetes services at national, regional and local levels. While NPID documents the challenges, there are also opportunities to learn from successful practice.

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Competing interests

HRM sits on a scientific advisory board for Medtronic (insulin pump manufacturer). The authors declare that there is no duality of interest associated with this manuscript.

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**FIGURE 1.** Variation in the percentage of women taking 5mg folic acid before conception in individual units. The top panel shows the median (IQR) percentage of women with Type 1 diabetes taking 5mg folic acid in individual clinics. The bottom panel shows the median (IQR) percentage of women with Type 2 diabetes taking 5mg folic acid in individual clinics.

**FIGURE 2.** Variation in the percentage of women achieving the NICE recommended target HbA1c levels of < 48 mmol/mol (6.5%) after 24 weeks gestation in individual units. The top panel shows the median (IQR) percentage of women with Type 1 diabetes achieving HbA1c < 48 mmol/mol (6.5%) in late pregnancy. The bottom panel shows the median (IQR) percentage of women with Type 2 diabetes achieving HbA1c < 48 mmol/mol (6.5%) in late pregnancy. Data are included only from 126 units with at least 10 valid HbA1c measurements for Type 1 diabetes and 103 units for Type 2 diabetes units.

**FIGURE 3.** A pregnant woman with Type 1 diabetes wearing the closed-loop system consisting of an insulin pump, continuous glucose monitor and a control algorithm housed on a mobile phone.
Table 1 National Pregnancy in Diabetes (NPID) audit data, collected from 172 maternity units during 2016

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<th>All</th>
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*Type of diabetes was not specified (n = 28), specified as monogenic (n = 33) or other (n = 10).
†Seven women had two pregnancies and there were 49 twin and 1 triplet pregnancies recorded among 3297 women, providing outcome data for 3356 pregnancies.