

# Evaluating Outcomes of Pregnancy in Diabetic Women

## Epidemiologic Considerations and Recommended Indicators

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Many programs have been applied in various settings to reduce adverse outcomes of pregnancy in women with diabetes. Efforts to standardize criteria and methods for evaluating these programs are relatively recent. Without such standardization, evaluation of the impact of many programs and comparisons among programs have not been possible. We review the suitability of available data sources for monitoring adverse outcomes of pregnancy in women with diabetes in light of epidemiological considerations relevant to selection of indicators of program impact. This article is intended to be a resource to help evaluate in a standardized fashion the impact of programs at a regional, state, or local level. We conclude that primary data (information collected by programs themselves) collected in a standardized manner are necessary for evaluation of programs for diabetes in pregnancy. Secondary data sources alone are of limited value for monitoring outcomes because of underreporting of maternal diabetes, especially in the absence of identified complications. Ultimately, the ability to rigorously assess the impact of efforts to improve outcomes of diabetes in pregnancy may depend on the creation of comprehensive statewide systems to identify women of childbearing age who have diabetes. *Diabetes Care* 11:281-87, 1988

**M**any programs have been applied in various settings to reduce adverse outcomes of pregnancy in diabetic women. Before recent efforts by the Centers for Disease Con-

trol (CDC; 1), criteria and methods for evaluating these programs had not been standardized; evaluation of the impact of many programs, and comparisons among programs, were therefore not possible. We review the suitability of available data sources for monitoring adverse outcomes of pregnancy in diabetic women; the article is intended to be a resource to help evaluate the impact of programs at a regional, state, or local level.

Evidence suggests that preexisting diabetes mellitus (PEDM) and gestational diabetes mellitus (GDM) should be treated as distinct entities when planning interventions and evaluations. The consequences of GDM are uncertain; morbidity and mortality associated with GDM may have been overestimated in many studies because of reporting biases. Although the problem of adverse perinatal outcomes in babies of mothers with PEDM is well documented, the relative rarity of PEDM limits the usefulness of many data sources for assessing program outcomes and produces challenges for program evaluation efforts.

We consider the use of both primary and secondary data for evaluation. *Primary data* refers to information collected by programs themselves. Examples of primary data include the registration forms and flow sheets maintained on each prenatal patient and hospital records of the labor and delivery. *Secondary data* refers to sources of information that are already being collected by other agencies but could be used for program evaluation. Examples of secondary data sources are vital statistics, computerized hospital discharge abstracts, and third-party billing data.

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### PREEXISTING DIABETES MELLITUS

Pregnancy in women with PEDM is associated with increased risk of several adverse outcomes. These adverse

outcomes include fetal and neonatal mortality and congenital anomalies (2–10); prematurity and its associated morbidity, including respiratory difficulties and jaundice (5–7,9–11); increased incidence and severity of respiratory distress syndrome (RDS) and hyaline membrane disease (related both to prematurity and to other independent factors associated with diabetes) (7,10–15); complications of macrosomia, birth injuries to infant and mother, and cesarean section to prevent shoulder dystocia (10–12,15–18); and neonatal hypoglycemia (10,15). Neonatal hypocalcemia and polycythemia are additional serious, but less common, complications in infants of diabetic mothers (10,15).

Of the adverse outcomes associated with pregnancy in women with diabetes, congenital anomalies deserve special attention. Major anomalies are estimated to cause two-thirds of perinatal mortality in PEDM (4,9). A dramatic reduction (up to 70%) in anomalies in diabetes-associated pregnancies has been demonstrated in clinical settings in which blood glucose control was maintained from before conception through the critical period of organogenesis (4,6,8,19). Not only can congenital anomalies be reduced in PEDM, but other diabetes-related perinatal mortality and serious morbidity can be prevented in these pregnancies (5,6,11). The role of glycemic control per se in reducing adverse outcomes other than congenital anomalies is less documented (6,7,15,20,21).

Macrosomia is not an adverse outcome in itself and is neither a sensitive nor specific indicator of preventable adverse outcomes of diabetes in pregnancy (1). Macrosomia occurs in many diabetic pregnancies managed optimally by all other criteria (6,7,21–23), and most macrosomic infants are born to mothers without PEDM or GDM (10,24).

**GESTATIONAL DIABETES**

Gestational diabetes mellitus, defined as the onset or first recognition of maternal glucose intolerance during pregnancy, is 5–10 times more common than PEDM during pregnancy (2,25–28). The significance of GDM, however, is unclear. Untreated GDM is widely thought to be associated with increased risk of several morbidities, including birth injury or cesarean section related to macrosomia (10,29,30), neonatal hypoglycemia (30), and RDS (11,29,30), but not to be associated with increased risks of congenital anomalies or preterm delivery (3,6,10,28,31,32). Rates of adverse outcomes associated with GDM may be inflated, however, due to selective underreporting of GDM in uncomplicated births. Controversy also exists regarding whether risks of morbidity in GDM can be reduced (6,7,21,23) and whether risks of mortality are increased in GDM (27,29,32,33). It is possible, but unproven, that undetected GDM is a cause of avoidable perinatal mortality. Until this information on GDM is available, relevant evaluation criteria

will remain unclear, and evaluation efforts should focus on programs designed for women with PEDM.

**QUANTITATIVE ISSUES**

The utility of any data source for evaluating a program is limited by the incidence and/or prevalence of the condition of interest and by the impact of the program. The maximum impact of programs designed to prevent adverse outcomes of diabetic pregnancy can be estimated from available population-based studies (Table 1).

The incidence of pregnancies complicated by PEDM ranges from 0.2% of pregnancies in the state of Washington in 1979 (2) to 0.5% of 17,500 pregnancies in Maine (34) and 0.78% in the National Natality and Fetal Mortality Surveys of 1980 (27). Estimates of the prevalence of GDM in pregnant women range between 1 and 5%, with 3% being widely accepted (23,25–27,35). Perinatal mortality rates for the nondiabetic population in the United States are ~1–2% (35). Estimates of perinatal mortality in infants of mothers with PEDM range from 2 to 10% (7,10,11,27,36). Mortality rates for infants of mothers with GDM are estimated to be approximately the same as those for infants born to mothers without GDM, i.e., 1–3% (3,21,23,29,31).

In the absence of special programs, major congenital anomalies (defined as defects requiring surgical correction to prevent death or disability or as causing developmental retardation) occur in 6–12% of births to women with PEDM (3,4,6–8,12). The rate of major congenital anomalies in both the general population and in infants of mothers with GDM is estimated to be 1–3% (3,6,27,33). Results from programs beginning before pregnancy, which emphasize education as part of a coordinated package of specialized services, suggest that

**TABLE 1**  
**Rates and estimated annual incidence of congenital anomalies and perinatal mortality in a population of 5 million people according to diabetic status of mothers**

	Total	Mothers without diabetes	Mothers with GDM	Mothers with PEDM
Live births (n)	80,000	77,000	2400	160–400
Major anomalies in live births (%)	1–3	1–3	1–3	6–12
Births with major anomalies (n)	800–2400	770–2300	24–72	10–48
Perinatal mortality rate (%)	1–2	1–2	1–3	2.2–10
Perinatal deaths (n)	800–1600	770–1500	24–72	4–40

Rates are based on the following assumptions: 1) annual birth rate is 1.6% of total population, 2) 0.2–0.5% of pregnancies are complicated by preexisting diabetes mellitus (PEDM), and 3) 3% of pregnancies are complicated by gestational diabetes mellitus (GDM). See text for sources of estimates.

anomaly rates in infants of mothers with PEDM can be reduced to rates similar to those of the general population (4).

Estimates of the incidence of congenital anomalies and of perinatal death associated with GDM are similar to those rates for the general population (Table 1). Thus, programs cannot expect to demonstrate changes in these rates for GDM.

By use of the projections shown in Table 1, a program with 100% efficacy reaching 100% of the population at risk in an area with a total population of 5 million people could reduce major anomalies in 160–400 babies by the excess incidence associated with diabetes [i.e., reduce anomalies associated with PEDM (10–48 anomalies/yr) to the same incidence as in the general population (2–12 anomalies/yr)]. Thus, with 100% coverage and 100% efficacy, a program might prevent up to 46 major anomalies annually in a region of 5 million people. By similar reasoning, a program with 100% coverage and 100% efficacy could reduce perinatal deaths by the excess associated with PEDM, that is, from 3.5–40 deaths to 2–8 deaths.

A wide range of incidence rates is reported for diabetes-associated congenital anomalies (6–12%) and perinatal mortality (2.2–10%; Table 1). Thus, a preventive program in a population of limited size might result in lower rates of anomalies or mortality due to diabetes but be unable to demonstrate a statistically significant reduction in annual rates. To increase statistical sensitivity, a program may need to aggregate data over several years or use data for an area more populous than the region served.

## POTENTIAL DATA SOURCES

**Vital statistics.** There is general agreement that vital statistics data in the United States are an excellent source of demographic information. Studies that have compared vital statistics with hospital records, however, suggest serious inadequacies in vital statistics as a source of medical information, with variability between states in the quality of particular data elements (36–40). Maternal diabetes as a complication of pregnancy is significantly underreported on birth certificates, especially for GDM and births without adverse outcomes and even for births complicated by serious morbidity such as congenital defects (1,27,36–38; J. Harris, Northern California Birth Defects Monitoring Program, personal communication). In analyses of the National Natality and Fetal Mortality Surveys of 1980, the incidence of births reported to be complicated by PEDM was 0.78% whereas the incidence reported for GDM was 0.38%, less than half the PEDM rate (27). This discrepancy is strong evidence for underreporting of GDM in vital statistics, because GDM is generally accepted to be 5–10 times more frequent than PEDM.

In states where there is no special place on the birth certificate to record the presence of diabetes in the mother,

underreporting of both PEDM and GDM is a serious problem. A 1984 study of vital statistics and hospital records found that >60% of diabetes-complicated births in South Carolina (where there is no diabetes check-off box on the birth certificate) were not recorded on birth certificates (37). Even in the state of Washington, where a maternal diabetes check-off box appears in the main body of the birth certificate, maternal diabetes is estimated to be underreported by at least 25% (37) and to be subject to numerous reporting biases (27,37,38). Maternal diabetes appears to be reported more completely when a perinatal death occurs and linkage of birth and death certificates is performed. A study of 1978 vital statistics and hospital data in South Carolina showed 79% reporting of maternal diabetes for diabetes-associated fetal deaths versus 22% for births (36). Furthermore, vital-statistics records do not distinguish reliably between PEDM and GDM. In Washington, 37% of birth certificates that noted maternal diabetes indicated the type of diabetes incorrectly (37).

Although there is a check-off box on the birth certificate for congenital anomalies, comparisons of birth certificates with hospital records have shown that major anomalies are reported at a rate of only 20–25% of their incidence according to hospital records, whereas minor anomalies are rarely noted on the birth certificate (J. Harris, personal communication). A study by H. Jamison of the California Department of Health Services compared birth certificates and hospital records for 458 births during 1979 at eight California hospitals. A total of 45 anomalies were found, of which 36 were recorded only in the hospital record, 2 were recorded only in the birth certificate, and 7 were recorded in both (A. Hexter, California Birth Defects Monitoring Program, personal communication). The California Birth Defects Monitoring Program has compared the reporting of anomalies in vital statistics, hospital discharge abstracts, and hospital records in a major study.

Reporting of morbidity on birth certificates is also unreliable for other neonatal morbidity, e.g., complications of labor and delivery and birth injury. Reporting of maternal morbidity other than cesarean section is also unreliable.

**Hospital discharge abstracts.** At most U.S. hospitals, discharge abstracts record standardized data on the characteristics of hospitalized individuals. Data usually available from hospital discharge abstracts include the patient's age, sex, race, and diagnosis; primary and multiple secondary diagnoses are entered. Thus, hospital discharge-abstract data are a potential source of information on incidence of anomalies and other morbidity for infants of mothers with diabetes.

According to hospital medical-records abstracters, reporting of PEDM on hospital discharge abstracts is probably good for obstetric and neonatal discharges in which morbidity is observed in the infant. We recently reviewed obstetric and neonatal discharge records at a major tertiary-care medical center for a 6-mo period in 1984. There were 16 hospital discharges of women after

delivery for which either diabetes or abnormal glucose tolerance was noted as a primary or secondary diagnosis. During the same period, there were only 12 discharges of newborns born at that center for which diabetes was noted as a primary or secondary diagnosis (P.B., J.S.; unpublished data). This suggests underreporting of infants of diabetic mothers (PEDM or GDM) in relation to reporting of maternal diabetes in delivery records.

Underreporting can spuriously inflate estimates of the incidence of anomalies in infants of diabetic mothers (by artificially lowering the denominator, the total number of diabetes-associated births). Gestational diabetes appears to be significantly underreported in both obstetric and neonate medical records in both tertiary-care centers and community hospitals, especially when no associated complication is apparent (1,27). The number of and selection criteria for multiple secondary diagnoses can vary considerably among institutions, as can the quality in general of reporting in discharge abstracts. Overall, however, hospital discharge data appear to be superior to vital statistics in reporting of maternal diabetes, especially for PEDM (36–38).

Discharge data are also a better source of information on major congenital anomalies than are birth certificates, because defects may be discovered between the time of completing the birth certificate and the time of discharge. Discharge abstracts, however, do not necessarily provide complete reporting of congenital anomalies, especially for multiple defects, minor defects, or those detected after discharge of the newborn. Furthermore, selective underreporting of maternal diabetes when no anomalies are detected remains a problem in use of this data source to estimate rates.

The chief limitation of hospital discharge abstracts for monitoring rates of RDS of the newborn or other diabetes-associated perinatal morbidity is the lack of consistent criteria among institutions for diagnosing these conditions. For example, hospital X may only diagnose RDS when a newborn requires assisted ventilation, whereas hospital Y might record RDS when the clinical record notes respiratory problems that require special diagnostic and therapeutic attention without assisted ventilation.

Criteria for diagnosing neonatal hyperbilirubinemia vary from blood levels  $>5$  to  $>15$  mg/dl (10). Some institutions report jaundice only if phototherapy or exchange transfusion is required, whereas others may report jaundice when clinically apparent even if it resolves with hydration before routine discharge. Hospitals also have different protocols for checking for neonatal hypoglycemia (10,38). Some nurseries prevent hypoglycemia in infants of diabetic mothers with routine administration of glucose. Neonatal hypoglycemia is rarely detected by symptomatology (10).

These inconsistencies in recording adverse outcomes of pregnancy other than anomalies are so large that comparisons of rates of occurrence of these conditions among hospitals may not be meaningful. The incidence

of individual morbidities within a defined program population may be monitored to detect changes over time when keeping diagnostic criteria constant; this implies primary data collection. Until standardized criteria for diagnosing and recording morbidity are in effect, neonatal morbidity incidence rates derived from hospital discharge abstracts are not useful as outcome measures for programs with deliveries occurring at more than one hospital.

**Hospital medical records.** In comparison with discharge abstracts, hospital medical records yield more clinical information on obstetric, neonatal, and infant hospitalizations and on occurrence of anomalies but may not include certain information such as presence of gestational diabetes in the mother or anomalies discovered in the baby on outpatient follow-up. The principal limitation of medical records as a data source is the considerable cost of abstracting data from this source. It is not feasible to perform in-hospital record reviews on all births or to reliably identify all the diabetes-related obstetric and neonatal hospitalizations. Data collection from hospital records of program participants may, however, be feasible for regional high-risk perinatal programs. This type of data collection could be integrated into routine program surveillance procedures.

**Hospital billing data.** Diagnostic information is not necessarily recorded, or recorded accurately, in most third-party billing data (40). The principal reason that information about diabetes is often not accurate in these sources is that diabetes is generally a secondary diagnosis, and there is a great deal of discretion in the reporting of secondary diagnoses (41). Third-party billing records are thus not a recommended source of data on diabetic pregnancy, for assessing pregnancy outcome or for assessing the size of the population at risk.

**Sources of data on ambulatory care.** The National Ambulatory Medical Care Survey provides national (but not state-specific) estimates for ambulatory visits in the U.S., including a sizable sample of obstetric visits. Coding of secondary diagnoses is likely to be inconsistent (J. DeLozier, National Center for Health Statistics, personal communication), however, which limits the utility of this data source. There is no uniformity in the procedures for listing diagnoses. Instructions for recording principal and secondary diagnoses are limited to directing the physician to list the diagnoses in order of decreasing importance, according to the physician's "best judgment at the time of the visit . . . of diagnoses that . . . may be tentative, provisional, or definitive." Instructions for recording "other significant current diagnoses" are also lacking in specificity; there is no instruction to list diabetes when present (42). There is no routine ambulatory medical survey on a statewide basis, although California, Minnesota, and other states have conducted surveys that include information on diabetes.

**Registries.** A registry of diabetic women of childbearing age in a region or state could provide incidence rates of pregnancy in diabetes and associated complications. Without a registry, there is no fully reliable means of

estimating program impact because the denominator of people at risk is unknown, as is a characterization of outcomes in people at risk who did not receive services.

There are no national or local registries of all diabetic patients, of all women with diabetes, of all pregnant women with diabetes, or of infants born to mothers with diabetes. The planned statewide registry of newly diagnosed insulin-dependent diabetes in girls <18 yr of age in Colorado, for example, could eventually serve as a basis for monitoring pregnancy outcomes in that state. Maine is in the process of establishing a registry of all diabetic women of childbearing age. Such registries on a state level provide options for monitoring outcomes of pregnancy in women with PEDM, both in those who do not receive program services and in those served. The expense of maintaining a registry, however, could delay implementation of this option.

The CDC maintains a national Birth Defects Monitoring Program that relies on information from hospital discharge abstracts, supplemented by reports from a few regions with special surveillance activities. Northern California and metropolitan Atlanta are among the few regions that have systems that include review of hospital records for surveillance of birth defects. Both systems can also link hospital discharge abstracts with more complete data from the hospital record.

## CONCLUSIONS

The task of measuring the impact of programs designed to reduce the adverse outcomes of pregnancy in women with diabetes is complicated by several factors that are related both to the outcomes of interest and to reporting practices. First, there is no secondary data source that accurately identifies all pregnancies complicated by diabetes; therefore, complication rates cannot be determined with secondary sources. Second, morbidity and mortality occur primarily in pregnancies in women with PEDM, which is relatively rare. Even for the best programs with the best data, it may be challenging to detect annual changes, given the relative rarity of the events being monitored. Third, GDM is far more common than PEDM, but GDM is seriously underreported in all existing population-based data sets (1,27,37), and the clinical significance of GDM is not yet well established. Fourth, even when maternal diabetes is reported in existing data sets, PEDM and GDM are not reliably distinguished, and reporting of the fetal/neonatal morbidities of interest is unreliable. For several morbid conditions (e.g., hypoglycemia, jaundice, and RDS), detection practices and/or diagnostic criteria are so variable that aggregated data for these diagnoses may not be meaningful.

Secondary data sources can provide information on two outcomes that may be useful in evaluating programs to reduce adverse outcomes in pregnancies with PEDM: congenital anomalies and perinatal mortality. Hospital

discharge abstracts, potentially available in most states through discharge-abstracting services, can provide data on the total number of congenital anomalies associated with diabetes. Discharge abstracts are not an adequate source to estimate the number of pregnancies associated with PEDM, so rates of congenital anomalies cannot be determined. Although most diabetes-associated anomalies will occur in pregnancies with PEDM rather than GDM, it would be desirable to review the medical records of the identified cases to verify PEDM.

Neonatal death certificates are an acceptable source for identifying neonatal deaths associated with maternal diabetes. As with hospital discharge abstracts, neonatal mortality rates cannot be determined for PEDM because the number of diabetic pregnancies is not known. When the number of diabetes-associated complications is small, aggregation of data from  $\geq 2$  yr can facilitate comparison of postintervention numbers with those of previous periods.

Programs for mothers with PEDM should include primary data collection to determine rates of major congenital anomalies and perinatal mortality in the women reached by the program. Because there will be no comparison group, these complication rates can only be compared to published data from areas without an intervention program. To increase the validity of such a comparison, it is crucial that programs identify and offer services to all women with PEDM in the area served, particularly those who are not already receiving optimal medical care; these are the women who might be expected to benefit most from an appropriate intervention. If they are not included, apparently low complication rates may be due to selecting women at lower risk.

The number of women with PEDM in the target area can be estimated by use of the age distribution for the area from census data and the best available estimates of the prevalence of diabetes and the pregnancy rate for PEDM in that area. These rates may be obtained from health surveys conducted by the state, or national estimates may be used. The number served should then be compared with this estimate of the total number in the target population.

Programs should collect primary data in standardized form at the time of contact with the patient. It is important to measure the demographic characteristics and risk factor status of the population served to verify that the program is reaching a representative or high-risk portion of the target population.

Measures of program activity (process measures) may be valid outcome indicators where studies have established a correlation between delivery of a given service or attainment of a targeted intermediate outcome (e.g., glucose control with self-monitoring of blood glucose from prepregnancy through the first trimester) and a desired health outcome (e.g., reduced incidence of major birth defects). Documenting the major risk characteristics of program participants (e.g., age, ethnicity, socioeconomic status, level of prior medical care, and major medical risk factors) is important to ensure that the pro-

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gram is not selecting people of inherently lower risk and thereby appearing to achieve desirable outcomes.

Ultimately, rigorous evaluation of the impact of programs designed to reduce the morbidity associated with diabetes in pregnancy will require the creation, on a statewide basis, of comprehensive systems to identify and track women of childbearing age who have diabetes. With a registry, for example, the denominator of people at risk could be known reliably, and rates of selected outcomes could be calculated for people receiving services and those not receiving services. Furthermore, a registry is an excellent way to ensure that women with PEDM are directed to appropriate health-care services.

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