

Cost-Benefit Analysis of Preconception Care for Women With Established Diabetes Mellitus

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OBJECTIVE— To determine whether the additional costs of preconception care are balanced by the savings from averted complications. Several studies have demonstrated the efficacy of preconception care in reducing congenital anomalies in infants born of mothers with pre-existing diabetes mellitus.

RESEARCH DESIGN AND METHODS— This study used literature review, consensus development among an expert panel of physicians, and surveys of medical care personnel to obtain information about the costs and consequences of preconception plus prenatal care compared with prenatal care only for women with established diabetes. Preconception care involves close interaction between the patient and an interdisciplinary health-care team as well as intensified evaluation, follow-up, testing, and monitoring. The outcome measures assessed in this study are the medical costs of preconception care versus prenatal care only and the benefit-cost ratio.

RESULTS— The costs of preconception plus prenatal care are \$17,519/delivery, whereas the costs of prenatal care only are \$13,843/delivery. Taking into account maternal and neonatal adverse outcomes, the net savings of preconception care are \$1720/enrollee over prenatal care only and the benefit-cost ratio is 1.86. The preconception care program remained cost saving across a wide range of assumptions regarding incidence of adverse outcomes and program cost components.

CONCLUSIONS— Despite significantly higher per delivery costs for participants in a hypothetical preconception care program, intensive medical care before conception resulted in cost savings compared with prenatal care only. Third-party payers can expect to realize cost savings by reimbursing preconception care in this high-risk population.

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Excellent blood glucose control before and during pregnancy in women with established diabetes is critical for the prevention of maternal and fetal complications (1–7). Preconception care helps women become informed about the demands of pregnancy complicated by diabetes, develop good general health practices, and achieve optimal glycemic control before conception through diet and strict glucose monitoring. The ultimate goal of preconception care is to permit delivery of an infant who is anatomically and physiologically normal and to avoid maternal complications of poorly controlled diabetes.

Infants of mothers with diabetes are at particular risk for malformations, which may cause death or require major surgery (3,6,8,9). Mills et al. (3) reported malformation rates of 4.9% for early registrants who achieved moderate glycemic control (85% of whom entered care before conception) compared with 9.0% for late registrants. To achieve even lower malformation rates requires tight glycemic control before conception. Combs and Kitzmiller (10) estimated that the congenital malformation rate across 5 studies (1,2,11–13) was 1.0% for 590 preconception care patients and 8.6% for 596 patients receiving prenatal care only.

Poor blood glucose control during pregnancy is also associated with increased risk of spontaneous abortion and certain maternal complications. Studies demonstrating the relationship between prenatal control of diabetes and improved maternal and neonatal outcomes have been reviewed elsewhere (14).

The cornerstone of preconception care is close interaction between the patient and an interdisciplinary health-care team, ideally composed of physicians (for both metabolic and obstetrical care), a diabetes nurse educator, a dietitian, a social worker, and other physician subspecialists, including ophthalmologist, cardiologist, and nephrologist. Physician care is generally reimbursed under health insurance, whereas preventive in-

Table 1—Standards of preconception and prenatal care for women with existing diabetes

General principles of preconception care	<p>Inform patient about the risks of pregnancy complicated by diabetes.</p> <p>Use birth control until excellent blood glucose level is achieved.</p> <p>Identify, evaluate, and treat hypertension, nephropathy, and retinopathy.</p> <p>Educate in glucose control and self-monitoring.</p> <p>Instruct in nutrition and diet.</p> <p>Provide social work intervention and counseling as needed.</p>
Excellent blood glucose control	
Prevent hyperglycemia at beginning of pregnancy	GHb within 4 SD of mean or postprandial capillary blood glucose level <9 mM (162 mg/dl).
Achieve normoglycemia during pregnancy	<p>Average premeal capillary glucose < 5.1 mM (92 mg/dl).</p> <p>Peak postprandial blood glucose <7.2 mM (130 mg/dl).</p>
Requirements for patient	<p>Follow eating plan developed with dietitian.</p> <p>Monitor urine ketone levels three times/wk.</p> <p>Monitor blood glucose levels with reflectance meter four times/day (once fasting and after each meal, or before meals and bedtime snack).</p> <p>Self-adjust insulin dosage.</p> <p>Meet regularly with health-care team to tune-up glucose control and diet.</p> <p>Identify and manage sources of stress that interfere with adherence to regimen.</p>

interventions and counseling provided by nurse educators, dietitians, and social workers are covered less often. If services provided by these health-care workers are not covered by third-party payers, it is less likely that these services will be provided to patients.

This study examines the financial implications of implementing rigorous standards of care before and during pregnancy among women with established diabetes. The benefits of reduced adverse outcomes are balanced against the additional resources expended for preconception care for all women with diabetes, many of whom may not deliver because of infertility, miscarriage, or a later decision not to become pregnant.

RESEARCH DESIGN AND

METHODS—This study used literature review, consensus development among an expert panel of physicians, and surveys of medical care personnel to obtain information about the costs and consequences of preconception care plus prenatal care (preconception care program) compared with prenatal care only (prenatal care only program) for women

with established diabetes. This information is incorporated into a cost-benefit analysis comparing the net costs and benefit-cost ratio associated with preconception plus prenatal care versus prenatal care only in preventing the adverse outcomes of pregnancy. To maintain a conservative bias against preconception care, we used lower range values for the benefits of preconception care and upper range values for its costs when there was uncertainty regarding specific parameters. All costs are presented in 1989 dollars.

The structure of preconception and prenatal care

We model a situation in which preconception care is reimbursed under one scenario and not reimbursed under the other. We assume a community containing 1000 women of child-bearing age who have diabetes. Further, we assume that state-of-the-art metabolic and obstetrical care is available in both programs. The only differences lie in when care is initiated and what health consequences result from this decision.

A key assumption in this analysis is that the prenatal care only program

differs from the preconception care program in that women seek obstetrical care only after becoming pregnant. Based on the experience of the panel members, we assumed that this would occur, on average, at 12 wk gestational age. Because fewer prenatal care only patients would be in good glycemic control, they would receive more intensive medical interventions, sometimes including hospitalization to implement programs of intensive insulin therapy.

Table 1 summarizes the components of the preconception care program described previously (15). Details of both programs can be found in the full report of this study (16).

The expert panel was comprised of 6 physicians who specialize in the care of high-risk women during pregnancy, particularly women with established diabetes. They completed questionnaires designed to elicit the optimal components of preconception care and ensuing prenatal care as well as prenatal care only. Published descriptions of preconception care programs were identified and used as models for questionnaire items (1,13,17).

Panel members provided infor-

mation on the frequency and length of visits provided by members of the interdisciplinary team; laboratory and diagnostic tests; medications and self-monitoring supplies; maternal hospitalization for problems associated with diabetes; and the lengths of stay for maternal adverse outcomes. Panel members' responses were summarized and consensus was achieved through group discussion. To verify the appropriate resource requirements for other personnel involved in providing preconception and prenatal care, separate questionnaires were developed to solicit information from 5 nurse educators, 6 dietitians, 4 social workers, and 6 physician subspecialists (nephrologists, ophthalmologists, and cardiologists) identified by panel members.

Panel members provided cost data from their hospitals for all personnel, laboratory and diagnostic tests, hospital days, medications, and supplies. Mean values were used in assigning a monetary value to resource use in both programs. Appendix 1 lists the mean component costs used in this analysis. Total program costs were calculated by multiplying the costs, frequency, and extent of resource use across all patient participants in each program. Detailed descriptions are available of estimated resource use, including number of minutes per provider, number of visits and telephone calls, and proportion of patients receiving each service (16).

Outcomes of preconception and prenatal care

We identified important adverse outcomes associated with pregnancy complicated by diabetes. Maternal adverse outcomes, their estimated incidence rates, and costs for the preconception and the prenatal care only groups are shown in Appendix 2 (12,18,34). Where possible, values from the literature were used. For those outcomes for which published information was scarce, the panel members were asked to estimate rates based on their experience.

Neonatal adverse outcomes are detailed in Appendix 3. It was assumed that women entering the prenatal care only program would do so after the critical period of organogenesis (5–8 wk gestation), thus achievement of good glycemic control during pregnancy would not affect the rate of congenital anomalies. Further, we assumed that the incidence rates for neonatal adverse outcomes in the preconception care program could be no lower than the rates experienced in the general population as reported in the Birth Defects Monitoring Program (19). This information is from 1187 hospitals between 1982 and 1985 that monitored 3,096,375 births (21% of all births in the U.S.).

Many of the rates for adverse neonatal outcomes under the prenatal care only program were derived from early data on pregnancy complicated by diabetes (8,9,20). The rates from Soler et al. (8) were used for most of the cardiac anomalies (transposition, tetralogy of Fallot, ventricular and atrial septal defects) because they represent more conservative (lower) estimates. These data are considered reliable estimates of current anomaly rates in prenatal only care because they reflect the impact of inadequate glycemic control in early pregnancy and are confirmed by more recent studies (3,12).

Economic consequences of adverse outcomes

The medical and long-term care costs for adverse outcomes were estimated on the basis of cost information obtained from the literature and the physician panel.

Maternal adverse outcome costs. For maternal adverse outcomes, the panel was asked to estimate the approximate length of stay for hospitalization, specifying the number of days in the ICU, if required. To this estimate we applied the average per diem charge for community hospitals and tertiary care centers (regular hospital day, \$620) (21). On average,

the cost of a day in the ICU is ~2.5 times the cost of a regular hospital bed day (22). Physician fees for hospital visits were estimated using average Blue Cross/Blue Shield reimbursement rates for specialists in the state of New York (hospital visit regular bed, \$70; ICU patient, \$143). (Blue Cross/Blue Shield, Medicare part B prevailing charges—fee screen year 1984, updated to 1989 dollars). Where appropriate, the physician reimbursement for procedures was included. For each hospitalization, we assume two additional outpatient visits at a rate of \$58/visit (21).

Neonatal adverse outcome costs—initial hospitalization. Cost data on neonatal adverse outcomes were obtained from several sources. The medical costs of severe congenital heart defects (tetralogy of Fallot and transposition of the great vessels) include hospitalization, diagnostic tests, medications, supplies, surgery, and physician fees for the initial corrective procedure (23). Because of the significant long-term costs associated with spina bifida costs, we include total lifetime direct medical costs, discounted to their net present value (24).

For all other conditions, no specific cost studies could be identified. Approximate costs for congenital anomalies, respiratory distress syndrome, and perinatal asphyxia were assigned using the charges for general categories of neonatal problems reported in a study based on California neonatal ICU billing (25). We used the following general categories: anomaly-medical, anomaly-surgical, cardiac-medical, medical-surgical, primary-medical, and respiratory distress syndrome. These charges were deflated by California local wage rate adjustment factors to represent national charges. For metabolic abnormalities and transient tachypnea, we used the costs for pediatric-modified DRGs applied to neonates (26). In assigning DRGs to specific conditions, we assumed that all neonates in this population would have a birth weight >2499 g.

Physician fees for the treatment

of neonatal adverse outcomes were incorporated in two ways. For all conditions falling within the general categories described above (25) we estimated that physician costs average 25% of hospital costs. For metabolic abnormalities and transient tachypnea, we conservatively estimated physician costs at the value of physician hospital visits, averaged between routine and ICU visits (\$106.50, Blue Cross/Blue Shield, Medicare part B prevailing charges—fee screen year 1984, updated to 1989 dollars), multiplied by the average length of stay for the appropriate DRG.

Neonatal adverse outcome costs—subsequent care. For those conditions requiring neonatal ICU treatment, we assumed that follow-up medical care costs during the first 3 yr of life would be higher than for infants not requiring ICU care (27). In addition to follow-up medical care costs to 3 yr of age, it was expected that lifetime costs for medical care, residential care, and community services would be higher for individuals with certain conditions associated with physical and developmental handicaps. To include these costs, we incorporated the estimates provided by Korenbrot (Korenbrot, unpublished observations) for children with medical and developmental disabilities. Updating these costs to 1989 prices yields discounted lifetime direct costs of \$508,835. These costs were applied to 80% of patients with hydrocephalus (28), all patients with caudal regression, and the 4.7% of patients with perinatal asphyxia who develop cerebral palsy (29).

Nonmedical direct costs. To estimate the value of patients' lost productivity associated with participating in either program, we used the wage rates and travel times reported in a study of nutrition services during prenatal care for diabetic patients and partners. Travel time was 43 min/visit and wage rates were \$22,183/yr for women and \$30,777/yr for their partners (30).

Cost-benefit analysis. A cost-benefit analysis was performed comparing total

program costs with the dollar value of all maternal and neonatal adverse outcomes examined in this study. The analysis does not include future lost productivity of women or their infants because the perspective of the third-party payer is taken. We computed two measures of cost-benefit: net benefits and the benefit-cost ratio.

Net benefits are calculated as the total dollar costs of the preconception care program subtracted from the total dollar costs of prenatal care only program. Total dollar costs equal the monetary value of delivering the preconception care or prenatal care only programs plus the consequences of the program, also expressed in monetary terms. Consequences are the medical costs of caring for maternal and neonatal adverse outcomes. Net benefits are the costs with the preconception care program subtracted from the costs without the preconception care program, as follows:

$$\text{Net benefits} = \left[\underset{(1)}{P_{\text{prenat}}} + \underset{(2)}{A_{\text{prenat}}} \right] - \left[\underset{(3)}{P_{\text{precon}}} + \underset{(4)}{A_{\text{precon}}} \right]$$

where (1) P_{prenat} = the program costs for the prenatal care only program; (2) A_{prenat} = the costs of all maternal and neonatal adverse outcomes resulting from the prenatal care only program; (3) P_{precon} = the program costs for the preconception care program; (4) A_{precon} = the costs of all maternal and neonatal adverse outcomes resulting from the preconception care program.

The second measure is the incremental benefit-cost ratio, which is the ratio of program outcomes to program inputs. It is calculated by dividing the difference in adverse outcome costs (2 - 4) by the difference in program inputs (3 - 1). This ratio depicts the costs or savings for each additional (hence, incremental) dollar invested in the preconception care program over and above the prenatal care only program.

$$\text{Incremental benefit-cost ratio} = \frac{(2 - 4)}{(3 - 1)}$$

Sensitivity analysis. The base case analysis represents our best estimates of costs

and outcomes for each program. To address the uncertainty inherent in many of the estimates used for this analysis, a series of one-way sensitivity analyses was performed to assess the impact on the results of changing the values of key variables. In one-way sensitivity analysis, the value of only one variable is changed at any one time, and all other values are held constant.

In addition to the series of one-way sensitivity analyses, a second type of sensitivity analysis was performed in which all values for the incidence of specific congenital anomalies in both programs were replaced with values from published clinical trials and evaluations of preconception programs. For this sensitivity analysis, costs for anomalies not available in the base case analysis were derived from data from the Hospital Cost and Utilization Project (31).

RESULTS

Structure of the programs

The panel estimated that the preconception care program would require no more than 20 visits over a 4- to 6-mo period with excellent glycemic control occurring in the first 2-3 mo, although some panel members felt that as few as 8 preconception visits would be more likely. The base case analysis assumes that 20 visits will be required on average. Only after glycemic control was achieved and maternal health status was evaluated would the couple be encouraged to conceive.

We assume 1000 women enroll in the preconception care program. After evaluation, 12.7% are advised not to get pregnant or decide that the risks of pregnancy are too great (32). We assume that those remaining have a 10% infertility rate, which is comparable with the general population (33), thus 785 women with diabetes become pregnant and enter prenatal care. Of these women, 15.5% experience spontaneous abortions (34)

Table 2—Costs of the programs

	Preconception care program		Prenatal care only program	
	Cost/enrollee	Cost/delivery	Cost/enrollee	Cost/delivery
Direct medical costs				
Preconception portion	\$2638	\$4092	—	—
Prenatal portion	\$6181	\$9587	\$9314	\$10,003
Delivery	\$2475	\$3840	\$3575	\$3840
Total program	\$11,294	\$17,519	\$12,889	\$13,843
Direct nonmedical costs	\$873	\$1355	\$708	\$761

and 2.9% have therapeutic abortions largely because of antenatally detected anomalies (12). A total of 645 women are expected to deliver in the preconception care program.

For the prenatal care only program, 1000 women of child-bearing age with diabetes are present in the community. Of these, 10% are infertile and thus will not incur medical care costs related to pregnancy. Of the 900 who become pregnant, we assume 19.9% in the prenatal care only program will experience spontaneous abortions before seeking care, thus, 721 enroll in the prenatal care only program (35). The average risk of spontaneous abortion for women who go through preconception care is 15.5% (34). For women using prenatal care only, 30% are in such poor control that their risk of spontaneous abortion is 30%. We assume that women in good control in the prenatal care only group will have a similar rate to the preconception group. The overall spontaneous abortion rate for the prenatal care only group is thus $15.5(0.7) + 30.0(0.3) = 19.9\%$. We assume that 6.9% of women in the prenatal care only group receive therapeutic abortions for antenatally detected anomalies (12), leaving 672 women to deliver in the prenatal care only program.

Costs and consequences of programs

The preconception portion of the preconception care program costs \$2638/

enrollee, given 20 visits before the first prenatal visit (Table 2). The prenatal portion of the preconception program has lower total costs and lower per enrollee costs than does the prenatal care only program because the care received by prenatal care only patients is initially more intensive to achieve rapid glycemic control.

In terms of total direct medical costs (including delivery), the preconception group incurs costs of \$11,294/enrollee and \$17,519/delivery. Cost per enrollee in the prenatal care only program is \$12,889 and cost per delivery is \$13,843. The difference between the two programs is \$1594 in per enrollee costs (with the preconception care program being less costly) and \$3676 in per delivery costs (with the preconception care program being more costly). The per delivery cost in the preconception care group is higher because more women receive medical services without going on to deliver.

In general, rates of adverse outcomes for preconception care patients were lower than for prenatal care only patients. Table 3 lists those adverse outcomes that contributed most to the cost savings of the preconception care program. Details on estimated incidence rates and costs are presented in Appendixes 2 and 3.

Cost-benefit analysis

Under the base case analysis, employing the costs and incidence figures described

above, the net benefits of preconception care are \$1720/enrollee (Table 4). The incremental benefit-cost ratio is 1.86 and indicates that for every additional dollar expended in the preconception care program, \$1.86 is saved in direct medical costs.

Sensitivity analysis

Four sets of sensitivity analyses were conducted. First, we changed the values of the incidence rates for all adverse outcomes. Second, we examined the impact of changing the number of women who become pregnant. Third, we changed the input costs for the programs. Fourth, we used malformation rates from published studies of preconception care as alternative inputs to the model.

Changing incidence rates. The first four sensitivity analyses examine the impact of using alternative values for the incidence rates of adverse outcomes (Table 5). Under all of these scenarios, the preconception care program remains cost saving.

Changing the number of women who become pregnant. In the base case analysis, some cost savings are attributable to fewer women delivering in the preconception care program than in the prenatal care only program. If the number of women in the preconception care program who are advised not to get preg-

Table 3—Incidence estimates and net savings for selected neonatal and maternal adverse outcomes for 1000 women with diabetes mellitus

Adverse outcomes	Incidence estimates (%)*		Net savings of preconception care program†
	Preconception care program	Prenatal care only program	
Maternal			
Spontaneous abortion	15.5	19.9	\$92,451
Poor diabetic control (initial)	5.0	25.0	\$338,715
Poor diabetic control (subsequent)	10.0	20.0	\$593,508
Other maternal adverse outcomes	—	—	\$177,002
Total costs			\$1,201,676
Neonatal			
Hydrocephalus	0.058	0.200	\$461,524
Transposition of great vessels	0.011	0.570	\$473,850
Tetralogy of Fallot	0.011	0.140	\$109,637
Coarctation of aorta	0.007	0.640	\$260,794
Caudal regression	0.0005	0.127	\$447,662
Respiratory distress	7.6	7.6	\$146,338
Transient tachypnea	2.2	4.8	\$171,772
Other neonatal adverse outcomes	—	—	\$444,460
Total costs			\$2,516,037

*Details on sources of information for all incidence estimates and estimates for all other conditions are provided in Appendixes 2 and 3.

†Expressed as the difference between the preconception care and prenatal care only programs.

nant is cut in half, from 12.6 to 6.3%, the benefit-cost ratio becomes 1.09. If the infertility rate in both groups is reduced by half, from 10 to 5%, the benefit-cost ratio rises to 2.06.

Changing input costs. In the base case analysis, we did not include any costs for outreach activities that may be required to encourage women to enter the programs. However, because many women and their physicians are unaware of the value of preconception care in improving pregnancy outcomes, outreach efforts may be necessary to achieve the outcomes described in this report. Outreach costs for the preconception care program have been estimated at \$800/person enrolled in the program (R. Kaufmann, K.S. Awankwah, N. Ausmus, M. Koehle, unpublished observations). If we assume outreach costs in the prenatal care only program to be half that required for the preconception group (\$400), the benefit-cost ratio becomes 1.48. If no outreach costs are assumed for the prenatal care only program, the benefit-cost ratio becomes 1.33.

In another sensitivity analysis, the Phibbs et al. (25) estimates of hospital costs for neonatal outcomes were replaced with lower hospitalization and physician costs based on pediatric-modified DRG costs for neonates. Using these more conservative (lower) estimates of medical care costs for adverse outcomes yields a benefit-cost ratio of 1.66 in favor of preconception care.

Another analysis included non-medical direct costs, the costs of lost productivity for patients and partners at-

tending clinic, which had not been considered in the base case analysis. Including nonmedical direct costs, the benefit-cost ratio decreased to 1.58.

Finally, we assumed that the number of preconception visits was reduced from 20 to 8. Several panelists felt that 20 visits was an overestimate and that most patients would require fewer visits during the preconception portion of the program. Leaving all other factors the same and reducing the number of physician visits and nurse educator visits

Table 4—Summary of cost-benefit analysis

	Preconception care program	Prenatal care only program
Program costs	\$11,294,100 (3)	\$9,296,900 (1)
Adverse outcomes		
Maternal	\$1,989,749	\$3,191,425
Neonatal	\$7,665,300	\$10,181,367
Subtotal	\$9,655,079 (4)	\$13,372,792 (2)

Net benefits = (1 + 2) - (3 + 4) = \$1,720,514 or \$1720/enrollee

Benefit cost ratio = (2 - 4)/(3 - 1) = 1.86

Table 5—Sensitivity analysis

Description of analysis	Net benefits		
	Per enrollee*	Per delivery†	Benefit-cost ratio‡
Base case	\$1721	\$2669	1.86
Changing incidence rates			
Multiply incidence rates for adverse outcomes in preconception care program by 1.5	\$1500	\$2328	1.75
Double incidence rates for adverse outcomes in preconception care program	\$1281	\$1988	1.64
Incidence rates for preconception care program are placed midway between original value and prenatal care only rates	\$665	\$1032	1.33
Divide incidence rates for prenatal care only program by 2	\$393	\$610	1.20
Changing the number of women who become pregnant			
Assume percentage advised not to conceive is 6.4% (half of base case)	\$258	\$373	1.09
Infertility rate is 5%	\$2022	\$2972	2.06
Changing input costs			
Add outreach costs: \$800 for preconception care and \$400 for prenatal care only programs	\$1209	\$1875	1.48
Add \$800 outreach costs only for preconception care program	\$920	\$1428	1.33
Include direct nonmedical costs	\$1358	\$2106	1.58
Assume the number of preconception visits is 8 rather than 20	\$2117	\$3284	2.32
Using published comparative malformation rates			
Replace malformation estimates with rates from all published clinical comparisons of preconception and prenatal care only	\$1668	\$2588	1.84
All published comparisons excluding Mills et al. (3)	\$2504	\$3884	2.25

*Assuming 1000 enrollees in the preconception care program and 721 in prenatal care only program.

†Assuming 645 deliveries in the preconception care program and 672 in prenatal care only program.

‡Based on per enrollee costs and benefits.

to 8 increased the benefit-cost ratio to 2.32.

Using published comparative malformation rates. As a final sensitivity analysis, we reviewed studies that reported malformation rates among women in preconception care programs compared with late registrants into prenatal care (2,3,11–13,36,37). This analysis uses the best available data from clinical studies that, although prospective, were not randomized (details on the specific anomalies used in this sensitivity analysis can be obtained from the authors). As a result, selection bias and other threats to internal validity are not controlled. The costs of maternal outcomes were not changed in this analysis. Table 6 lists the overall malformation rates for each study. The benefit-cost ratio resulting

from this analysis was 1.84 when all studies were included. The level of glycemic control appears to have been less stringent in one study (3) than in the others analyzed herein. When this study

was excluded, the benefit-cost ratio was 2.25.

CONCLUSIONS— This study suggests that comprehensive preconception plus

Table 6—Congenital anomalies based on review of comparative studies

	Cases with congenital anomalies/total cases (malformation rates [%])	
	Preconception care	Late registrants
Fuhrmann et al. (37), 1986	1/128 (0.8)	22/292 (7.5)
Goldman et al. (2), 1986	0/44 (0.0)	3/31 (9.7)
Mills et al. (3), 1988	17/347 (4.9)	25/279 (9.0)
Steel et al. (13), 1990	2/143 (1.4)	10/96 (10.4)
Kitzmiller et al. (12), 1991	1/84 (1.2)	12/110 (10.9)
Rosenn et al. (36), 1991	0/28 (0.0)	1/71 (1.4)
Total	23/971 (2.4)	78/940 (8.3)

prenatal care for women with established diabetes can result in significant direct medical cost savings compared with prenatal care only. These savings result largely from prevention of the most expensive adverse events—congenital anomalies. Because no population-based studies have examined the economic impact of preconception care, we relied on secondary data to provide estimates of the incidence of specific birth defects and other adverse events and their costs. Further, we found no consensus in the literature and in practice on what constitutes preconception care. To address this data limitation, 6 clinicians who are expert in the provision of care to pregnant women with diabetes developed a consensus model of preconception plus prenatal care. Their efforts have resulted in a statement of preliminary standards of care (15) illustrated in Table 1, which provide the basis for estimating preconception program costs. As structured by this panel of physicians, such care necessitates the involvement of a multidisciplinary team of physicians, nurse educators, dietitians, and social workers engaged in treatment, education, and support of the diabetic woman.

This study has several strengths that make its estimates of benefits and costs robust and generalizable. First, the intervention used in this model is intensive and costly, thus providing a conservative bias in the savings associated with preconception care. This study shows that across a wide variety of assumptions, even intensive preconception care can result in significant cost savings over and above prenatal care only for women with established diabetes.

Second, when there was uncertainty regarding values for particular variables, we maintained a conservative bias to underestimate the benefits of preconception care and overestimate its costs. Despite this conservative bias, preconception care remained cost saving.

Third, rather than relying on the

outcomes of any one program, we used outcome rates for individual malformations from large population-based studies whenever possible. Because congenital malformations are rare even in high-risk populations, the incidence of these adverse events could potentially be misestimated. Furthermore, the high costs associated with a single malformation may lead to overestimation of costs. Using population-based figures and results from studies with large sample sizes avoids these pitfalls. Despite the differences in methodology, our estimates are comparable with other data. For example, the total major congenital malformation rate (summing the rates for each program) in this study is 0.402% in the preconception care program and 3.241% in the prenatal care only program. Both rates are lower than the overall malformation rates reported by others because we focused primarily on diabetes-associated anomalies. The following abnormalities have been reported among infants born of women with diabetes but were not included here because of lack of specific incidence data, relatively low per case costs, or because the abnormality is not specific to diabetes: diaphragmatic hernia, microcephaly, holoprosencephaly, patent ductus arteriosus, cardiomegaly, duodenal atresia, hypospadias, inguinal hernia, pseudohermaphroditism, small left colon syndrome, single umbilical artery, cleft palate, talipes, and various other urogenital, skeletal, eye, and ear anomalies. In addition, our figures are strictly literature-based, compiled by assessing each anomaly separately.

Nonetheless, the malformation rate in the prenatal care only program is eight times higher than in the preconception care program. This is the same relative risk reported in the meta-analysis by Combs and Kitzmiller (10). Furthermore, when congenital malformation rates from published studies (Table 6) were substituted for the population-based rates, the results were remarkably

similar. The validity of these results is further corroborated by another study of the cost-effectiveness of preconception care that reported a benefit-cost ratio of \$5.19 for a program in California (38). Although our results indicate that this ratio may be an overestimate compared with results based on population-based figures, the conclusions drawn from the two studies are still consistent—preconception care in this population can result in cost-savings.

This study focused primarily on direct medical costs; however, it would have been possible to estimate the indirect costs and benefits of the program. In health care, indirect costs are most often measured as the value of lost productivity attributable to morbidity or mortality. Preconception care led to fewer congenital malformations, therefore a greater number of infants would be able to lead productive lives. Had indirect costs and benefits been incorporated, the value of the disparity between the programs would have been even greater and larger cost savings would have been demonstrated. As a result of not including indirect costs, we have underestimated the total impact of preconception care by focusing solely on the economic impact within the health-care and social service sectors.

This study is limited in that it assumes that all patients who are eligible will enroll in the programs and remain in the programs throughout the course of pregnancy. Because of the rigors of preconception care, nonadherence would have the effect of increasing the rates of adverse outcomes while incurring nearly the same level of services and costs. We address the problem of nonadherence in two ways. First, we did not assume that all women would achieve excellent glycemic control in the preconception care program. The estimates of maternal adverse outcomes for the preconception care program include the costs of hospitalization for poor glycemic control and diabetic ketoacidosis, albeit at a rate lower than the prenatal care only group.

Second, the sensitivity analyses based on higher estimates of adverse outcomes indirectly estimate the impact of lower program efficacy with unchanged program costs.

A second limitation faced by this study is the reliance upon secondary data. Although the true economic implications of preconception care can only be determined through prospective studies, the conservative nature of this analysis probably provides an underestimate of cost savings.

This study indicates that preconception care aimed at encouraging the woman with established diabetes to achieve optimal control of her condition before pregnancy can result in significant direct medical cost savings. To assure that women with pre-existing diabetes receive medical treatment that adheres to the highest standards of care (39), physicians, diabetes educators, dietitians, and social workers must work in concert to provide state-of-the-art preventive interventions aimed at reducing adverse outcomes associated with pregnancy complicated by diabetes. Reimbursement for comprehensive diabetes and pregnancy care by third-party payers is also important in assuring that women with diabetes have access to the level of care required to prevent adverse outcomes for themselves and their infants. Based on these results, third-party payers can expect to realize cost-savings by reimbursing preconception care in this high-risk population.

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Appendix 1—Monetary costs applied to the programs*

Personnel (cost/h†)	
Metabolic care (MD)	\$47.60
Obstetrical care (MD)	\$62.70
Education (RN)	\$16.96
Social work	\$16.02
Nutrition	\$13.23
Ophthalmologic (MD)	\$82.30
Renal (MD)	\$47.60
Cardiac (MD)	\$64.98
Laboratory tests (cost/test)	
Rubella	\$22.81
CBC plus platelets	\$22.65
BUN	\$11.39
Serum creatinine	\$16.30
Urinalysis	\$13.59
Urine culture	\$52.98
24-h urine protein	\$22.32
24-h urine creatinine	\$25.14
HbA _{1c}	\$36.81
Hepatitis B surface antigen	\$35.69
VDRL	\$12.88
HIV	\$21.84
TSH, T ₃ , T ₄	\$104.15
Type and Rh	\$34.22
Antibody screen	\$40.18
Maternal serum α -fetoprotein	\$42.97
Other tests (cost/test)	
Electrocardiogram	\$62.93
Ultrasound	\$277
Nonstress test	\$137
Contraction stress test/biophysical profile	\$262
Fetal echocardiogram	\$462
Amniocentesis	\$519
Supplies	
Human insulin	\$12.87/1000 U
Syringes	\$10.83/100
Blood glucose monitoring strips	\$32.55/50
Lancets	\$16.92/200
Reflectance meter	\$167.50/each
Glucagon kit	\$23.34 /kit
Urine ketone monitoring strips	\$12.64/100
Oral contraceptives	\$15.67/mo
Other costs	
Outreach, preconception care program	\$800/person†
Vaginal delivery	\$2842 (40)
Cesarean delivery	\$5694 (40)
Nondirect medical costs (30)	
Patient	\$10.80/h
Significant other (male)	\$14.40/h
Travel time (patient)	\$7.74/visit
Travel time (significant other)	\$10.32/visit

*All costs based on surveys completed by financial officers in the panel members' hospitals, except where indicated; means reported.

†Based on reported hourly wages; fringe benefits of 25% and an overhead rate of 5% were applied.

‡R. Kaufmann, K. S. Awankwah, N. Ausmus, M. Koehle, unpublished observations.

Appendix 2—Incidence and costs of maternal adverse outcomes

	Incidence (%)		Costs	
	Pre-conception care	Prenatal care only	Hospital*	Physician†
Spontaneous abortion	15.5 (34)	19.9‡	\$620	\$287/\$706
Therapeutic abortion	2.9 (12)	6.9 (12)	\$620	\$287/\$758
Hospitalization for poor glycemic control				
Initial	5.0§	25.0§	\$1860	\$427
Subsequent	10.0§	20.0§	\$7440	\$1057
Diabetic ketoacidosis	1.5	3.0	\$5270	\$719
Hypoglycemic coma	0.3#	0.9	\$1240	\$917
Pyelonephritis	0.7#	2.1	\$2480	\$597
Diabetic retinopathy ^d				
Laser treatment	2.5	2.5	—	\$1820
Vitrectomy	0	0.1	\$1860	\$4382/\$427
Pre-eclampsia	10.5 ^b	10.5 (18)	\$6200	\$917
Eclampsia	0.2 ^b	0.2	\$4650	\$649
Pre-term labor	6.7 ^b	6.7 (18)	\$4340	\$707
Premature rupture of membranes	5.4 ^b	5.4	\$4340	\$707
Cesarean section	35.0§	35.0§	\$5694 ^c	—

Citations are in parentheses.

*Hospital costs based on panel estimates of days in hospital and cost data from Health Insurance Association of America (21) and OTA (22).

†Physician hospital visits/procedure costs reimbursed to physicians (based on data on Medicare part B prevailing charges obtained from Blue Cross/Blue Shield).

‡See METHODS.

§Panel estimate.

||Assume 50% of prenatal care only rate.

¶From L. Cousins and J. L. Kitzmiller California Diabetes and Pregnancy Program Data Committee, 1986-1988, unpublished observations.

#Assume 33% of prenatal care only rate.

^aL. Rand, unpublished observations.

^bAssume same as prenatal care only.

^cIncludes hospital costs and physician fees, based on Health Insurance Association of America (40).

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Appendix 3—Incidence and costs of neonatal adverse outcomes

Adverse outcome	Incidence (%)			Costs		
	Preconception care	Prenatal care only	Hospital*	Physician†	Care to 3 yr‡	Lifetime
Anencephaly	0.029 (19)	0.300 (9)	\$15,799	\$3950	—	—
Spina bifida	0.048 (19)	0.170 (9)	—	—	—	\$103,506§
Hydrocephalus (associated handicap [80%])	0.058 (19)	0.200 (9)	\$41,032	\$10,258	\$3263 (20%) \$21,445 (80%)	— \$508,835
Transposition of great vessels	0.011 (19)	0.570 (8)	\$92,400	—	\$33,722	—
Tetralogy of fallot	0.011 (19)	0.140 (8)	\$92,400	—	\$33,722	—
Ventricular septal defect	0.170 (19)	0.285 (8)	\$31,900	\$7975	\$3263	—
Atrial septal defect	0.020 (19)	0.285 (8)	\$31,900	\$7975	\$3263	—
Coarctation of aorta	0.007 (19)	0.640 (20)	\$31,900	\$7975	\$21,445	—
Renal agenesis	0.018 (19)	0.028 (9)	\$15,799	\$3950	—	—
Ureter duplex	0.003 (9)	0.070 (9)	\$15,799	\$3950	—	—
Cystic kidney	0.013 (9)	0.056 (9)	\$41,032	\$10,258	\$21,445	—
Hydronephrosis	0.007 (9)	0.028 (9)	\$41,032	\$10,258	\$21,445	—
Anal/rectal atresia	0.013 (9)	0.042 (9)	\$41,032	\$10,258	\$3263	—
Caudal regression	0.0005 (9)	0.127 (9)	\$79,550	\$19,637	\$21,445	\$508,835
Hyperbilirubinemia	20¶	20*	\$2800	\$479	—	—
Hypoglycemia	20¶	20*	\$2800	\$479	—	—
Hypomagnesemia	8¶	8*	\$2800	\$479	—	—
Hypocalcemia	20¶	20*	\$2800	\$479	—	—
Perinatal asphyxia (associated cerebral palsy)	6 (41,42) 0.282 (29)	6 (41,42) 1.200 (29)	\$22,328 —	\$5582 —	— —	— \$508,835
Severe respiratory distress syndrome	7.6 (43)	7.6*	\$54,624	\$13,656	\$3263	—
Less severe respiratory distress syndrome	0.75 (43)	0.75*	\$22,328	\$5582	—	—
Transient tachypnea	2.2 (44)	4.8 (44)	\$5460	\$792	—	—

Citations are in parentheses.

*Hospital costs based on Phibbs et al. (25) and Lichtig et al. (26).

†Physician hospital visits and procedure costs reimbursed to physician (based on data on Medicare part B prevailing charges obtained from Blue Cross/Blue Shield).

‡Shankaran et al. (27): \$3,263, mild disability \$21,445, moderate disability; \$33,722, severe disability.

§Medical care costs only (24).

||C. C. Korenbrot, unpublished observations.

¶Panel estimate.

*Assume the same as preconception care.

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