OBSTETRICS

Do postal reminders increase postpartum screening of diabetes mellitus in women with gestational diabetes mellitus? A randomized controlled trial

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OBJECTIVE: Women with previous gestational diabetes mellitus rarely receive the recommended 2-hour oral glucose tolerance test (OGTT) after delivery. We sought to determine whether postal reminders to be sent after delivery to a patient, her physician, or both would increase screening rates.

STUDY DESIGN: Patients were assigned randomly to 4 groups: reminders sent to both physician and patient, to physician but not patient, or to patient but not physician or no reminders were sent. The primary outcome was the proportion of patients who underwent an OGTT within 1 year after delivery. The secondary outcome was the performance of other postpartum screening tests.

RESULTS: OGTT rates were significantly increased in the physician/patient reminder group (49/81 women; 60.5%), in the patient-only reminder group (42/76 women; 55.3%), and in the physician-only reminder group (16/31 women; 51.6%) compared with the no reminder group (5/35 women; 14.3%; $P < .05$).

CONCLUSION: Postpartum reminders greatly increased screening rates for women with gestational diabetes mellitus.

Key words: gestational diabetes mellitus, glucose tolerance test, postpartum testing, reminder

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Gestational diabetes mellitus (GDM), the onset or recognition of carbohydrate intolerance in pregnancy, affects approximately 3% of nonaboriginal pregnant women in Canada.[1,2] Although the focus on the detection and treatment of GDM has been on obstetric outcomes, the high risk of the development of diabetes mellitus in women who are identified with GDM may be the most important population health reason for screening in pregnancy.[3] Most of these women will experience type 2 diabetes mellitus, with rates continuing to rise dramatically the first 5 years after delivery, regardless of other risk factors for insulin resistance.[4] A smaller proportion will experience type 1 diabetes.[5]

Most expert committees, which includes the Canadian Diabetes Association (CDA), recommend screening for diabetes mellitus in all women who have had GDM 6 weeks to 6 months after delivery with an oral glucose tolerance test (OGTT) as the preferred screening test.[3,6-8] The use of a fasting plasma glucose alone as the screening test for diabetes mellitus after delivery will miss approximately one-third of the development of diabetes mellitus in women with previous GDM and will not allow for the detection of impaired glucose tolerance, which is a strong predictor of cardiovascular disease and progression to type 2 diabetes mellitus.[9-11]

All studies have demonstrated a very low adherence to postpartum screening recommendations.[12-14] There are numerous reasons that women may not be screened in the postpartum period, including fragmentation of care, poor communication between providers, competing demands for time, transient population, and limited knowledge of importance. Previous research has shown patient reminders that are mailed in other clinical areas (eg, cancer screening) may increase adherence with screening recommendations,[15,16] and physician-directed, patient-specific decision support systems may improve the management of chronic health conditions.[17] Patient-specific reminders for women with GDM have not been studied previously. Given our previous finding that women are not being screened after delivery as part of usual care, we sought to determine whether postal reminders that are sent after delivery to a patient, to her physician, or to both would increase postpartum screening, according to the CDA guidelines.

Materials and Methods

This 2 × 2 factorial randomized controlled trial was performed at the Ottawa Hospital, a university-affiliated tertiary center in Ottawa, Ontario, Canada, that provides services to a catchment area of 750,000 people and performs 8000 deliv-

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eries each year. In addition to patients of our hospital, most women in the region who are treated with insulin for the management of GDM are referred for ongoing treatment and delivery at the Ottawa Hospital by obstetrician-gynecologists in conjunction with diabetic specialists as required. All physician visits, medical care, and diagnostic testing are covered by our provincial health insurance plan. All primary care is provided by family physicians.

All women, regardless of age, who attended the High Risk Obstetrical Unit between August 29, 2002, and March 31, 2005, for treatment of GDM and who provided written informed consent were considered for inclusion in the study. Patients were excluded for the following reasons: no family physician, the family physician already had a patient enrolled, the patient was already enrolled from a previous pregnancy, the pregnancy was not delivered at the Ottawa Hospital, there was no live birth, or contact was lost with the patient or her family physician for the end of study survey. Patients who were potentially eligible were recruited with their consent by the healthcare team during antenatal clinic visits. Final eligibility for the study was verified during the postpartum period by the study coordinator to confirm a live birth. The protocol was approved by the ethics committee of the Ottawa Hospital and registered with clinical trials.gov NCT00212914.

Randomization was performed with a computer-generated randomization list, and patients who met the eligibility criteria were assigned randomly in a 2:1 fashion of patient postal reminder to physician postal reminder, which resulted in 4 groups: (1) reminders sent to both physician and patient, (2) reminders sent to the physician but not to the patient, (3) reminders sent to the patient but not to the physician, or (4) no reminder sent (usual care). The physician postal reminder included the CDA recommendation and a patient-specific recommendation from the GDM health care team to screen the patient during the postpartum period for diabetes mellitus with an OGTT. The patient postal reminder reminded the patient of the importance of screening and contained the laboratory requisition to complete a screening OGTT. When reminders were sent to both the patient and the physician, the physician reminder was modified to inform the physician that the patient had received a requisition for the recommended screening test. Postal reminders were sent once to the patient and/or the physician approximately 3 months after delivery to conform with the recommended screening time period of 6 weeks to 6 months. The usual care group did not receive any information from the study regarding postpartum screening. The investigators and statistician were blinded to group allocation because the patients were not seen routinely after delivery in follow-up.

We made a number of assumptions in the sample size calculation. First, previous research has demonstrated that multiple interventions are more likely to change behavior than a single intervention.[18,19] Thus, the combination of patient and physician letter should lead to higher screening rates than either intervention alone. Second, we assumed that the effect of the 2 interventions would be independent of 1 another. Last, we performed a 2:1 patient/physician randomization because we assumed that physicians would be more likely to comply with recommendations delivered at the time the decision is made than patients who received the recommendation. Based on our clinical experience and some evidence on physician behavior and the uncertainty regarding patient response to recommendations, we assumed that the reminder that was sent to the physician would be more effective than a reminder that was sent to the patient, which would result in a smaller sample of physicians than patients who were required to meet statistical significance.[17] We assumed a screening rate of 5% in the control group, based on our previous work, and a combined screening rate of 35%.[12] A total sample size of 220 patients with a 2:1 randomization for the patient intervention vs the physician intervention was calculated. The study was powered to detect a difference in proportions among the 4 groups, assuming a power of 80% and an alpha error of 5%.

The primary outcome was the proportion of patients who were screened for diabetes mellitus with an OGTT within 1 year after delivery.

Secondary outcomes were the proportion of patients who were screened for diabetes mellitus with another test: venous fasting glucose, venous random glucose, glycosylated hemoglobin, or any combination of these.

Physicians and patients who were eligible for inclusion in the study were contacted 3 times for poststudy survey follow-up: the physician by fax, telephone, and mail; the patient was contacted by telephone twice and by mail once.

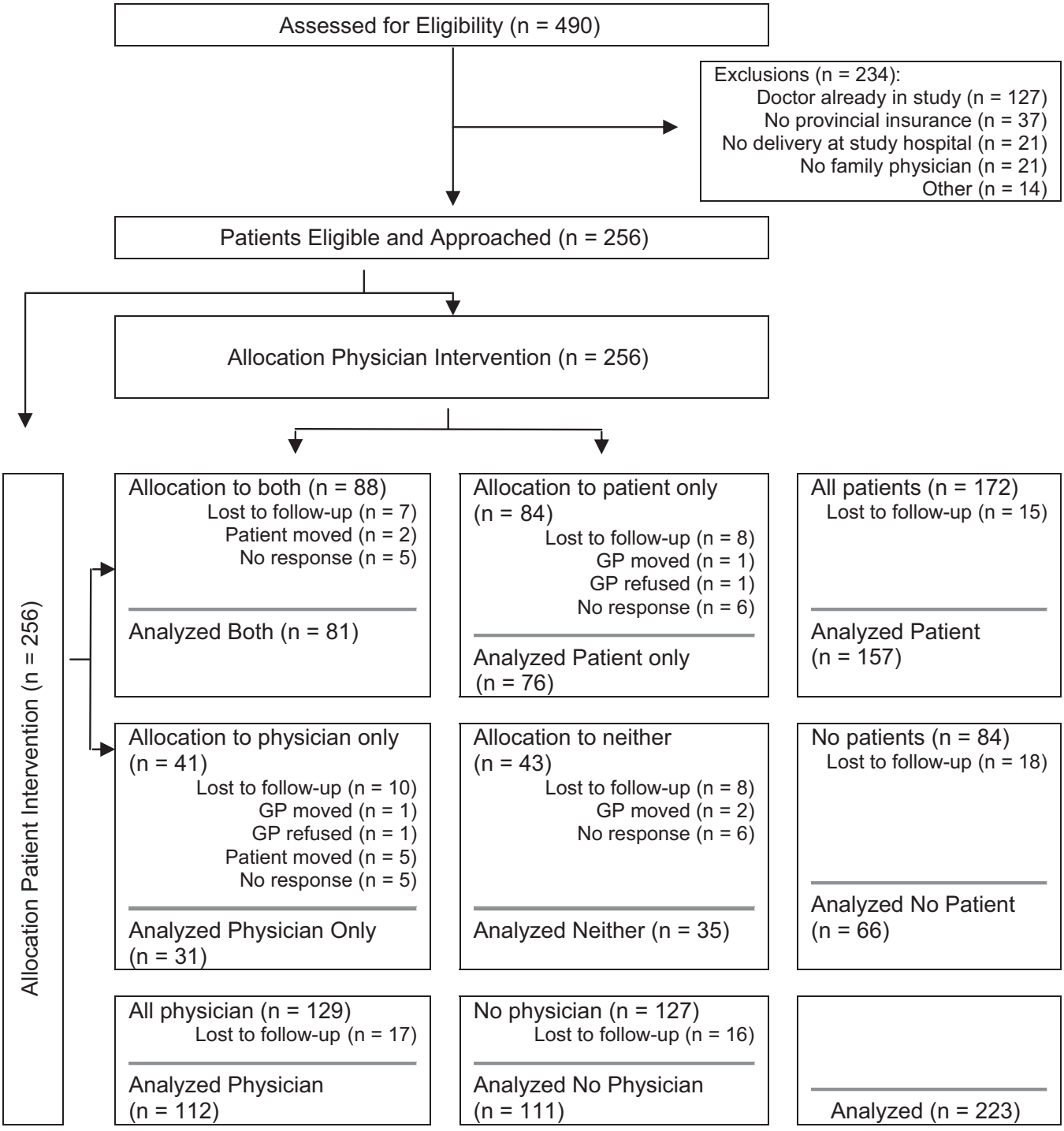
To determine whether a patient received screening, 3 different sources of information were used: screening results that were obtained by the study or by the physician or patient response to the poststudy survey screening question. To avoid underestimation of screening in the usual care group, patients were considered lost to follow-up and excluded from the primary analysis if no screening result was obtained and if the physician and patient did not respond to the survey.

A sensitivity analysis that made alternative assumptions for patients who were lost to follow-up was performed to analyze the robustness of the results because the primary analysis was not intention to treat.

Baseline maternal and reproductive history characteristics that have been shown previously to be associated with development of diabetes mellitus were collected. Obstetric and neonatal outcomes and physician characteristics that might lead to increased screening were also collected.

A Mantel-Haenszel χ^2 test statistic for overall comparisons of the proportions of the 4 groups was performed. Multivariate logistic regression analyses that included the dependent variable screened with an OGTT were performed. The interventions (physician or patient) and the combination of the interventions (interaction) were included in the model. Manual backward elimination was used for the other covariates ($P < .05$); odds ratios

FIGURE
CONSORT flow diagram



CONSORT, Consolidated Standards of Reporting Trials; *GP*, general practitioner.
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(ORs) that were reported in the final model were adjusted for the covariates that remained in the final model. Data were analyzed with SPSS (version 13; SPSS Inc, Chicago, IL). This analysis was repeated for each secondary outcome.

Subgroup analyses were performed if an interaction (combination effect) of the intervention was statistically significant. The effect of the physician intervention was evaluated in the following 2 subgroups: all patients who received a re-

TABLE 1
Sample characteristics and outcomes by randomized group

Variable	Reminders: Both (n = 81)	Patient only (n = 76)	Physician only (n = 31)	Neither (n = 35)	Total (n = 223)
CHARACTERISTICS					
Maternal					
Age ≥ 30 y	59 (72.8)	59 (77.6)	26 (83.9)	29 (82.9)	173 (77.6)
Body mass index ≥ 30 (kg/m^2)	30 (37.0)	18 (23.7)	9 (29.0)	16 (45.7)	73 (32.7)
White	48 (59.3)	44 (57.9)	19 (61.3)	26 (74.3)	137 (61.4)
Smoking in pregnancy	11 (13.6)	5 (6.6)	2 (6.5)	4 (11.4)	22 (9.9)
Postsecondary education	62 (76.5)	63 (82.9)	24 (77.4)	33 (94.3)	182 (81.6)
Primigravida	26 (32.1)	23 (30.3)	7 (22.6)	14 (40.0)	70 (31.4)
Family history of T2 diabetes mellitus	37 (45.7)	38 (50.0)	22 (71.0)	19 (54.3)	116 (52.0)
Previous GDM	8 (9.9)	10 (13.2)	7 (22.6)	7 (20.0)	32 (14.3)
GDM treated with insulin	48 (59.3)	44 (57.9)	19 (61.3)	26 (74.3)	137 (61.4)
Physician					
Female	45 (55.6)	46 (60.5)	25 (80.6)	20 (57.1)	136 (61.0)
Canadian graduate	61 (75.3)	57 (75.0)	27 (87.1)	30 (85.7)	175 (78.5)
Baby					
Preterm delivery	12 (14.8)	7 (9.2)	4 (12.9)	4 (11.4)	27 (12.1)
Birthweight > 4000 g	6 (7.4)	12 (15.8)	8 (25.8)	6 (17.1)	32 (14.3)
Cesarean section	33 (40.7)	25 (32.9)	10 (32.3)	18 (51.4)	86 (38.6)
OUTCOME					
OGTT[a]	49 (60.5)	42 (55.3)	16 (51.6)	5 (14.3)	111 (47.6)
Fasting glucose[a]	51 (63.0)	54 (71.0)	21 (67.7)	14 (40.0)	140 (59.5)
Random glucose	4 (4.9)	9 (11.8)	0 (0)	1 (2.8)	14 (6.0)
Glycosylated hemoglobin	7 (8.6)	9 (11.8)	7 (22.6)	6 (17.1)	29 (12.3)
Any test[a]	61 (75.3)	60 (78.9)	22 (71.0)	16 (45.7)	159 (67.6)

GDM, gestational diabetes mellitus; *OGTT*, oral glucose tolerance test.
Values are number (%) for a positive response, unless stated otherwise.
[a] $P < .05$.
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minder or no patients who received a reminder. The effect of the patient intervention was evaluated in the following 2 subgroups: physicians who did or did not receive a reminder.

RESULTS

Participant flow and follow-up

From August 2002 to March 2005, 490 patients who were identified before delivery agreed to participate in the study. Of these, 234 patients were excluded on the basis of enrollment criteria; an additional 33 patients were lost to follow-up and were excluded from the analysis, which left a study sample size of 223 patients (Figure).

Primary and secondary outcomes

Baseline demographics are outlined in Table 1 by allocated intervention with no significant differences among groups. The proportion of patients in each of the 4 groups who were screened with an OGTT, which was the primary outcome, was significantly different among groups with 49 of 81 patients (60.5%) being screened when both reminders were sent, 42 of 76 patients (55.3%) being screened when the patient received a reminder, 16 of 31 patients (51.6%) being screened when the physician received a reminder, and only 5 of 35 patients (14.3%) being screened with the recommended test when reminders were not sent ($\chi^2 = 22.3$; $P < .05$; Table 1). For the secondary outcomes, the proportions that were screened were also significantly different when the screening test that was

TABLE 2
Logistic regression models for screening, according to intervention

		OR (95% CI)		
Variable	**Intervention**	**Primary analysis**	**Sensitivity analysis 1[a]**	**Sensitivity analysis 2[b]**
OGTT	Both	5.2 (1.4-19.6)	3.4 (1.1-10.1)	3.9 (1.1-13.9)
	Physician	8.4 (2.4-28.5)	4.0 (1.6-9.9)	4.8 (1.6-14.9)
	Patient	8.7 (2.9-25.6)	3.4 (1.6-7.4)	7.6 (2.7-21.3)
	Neither	1.0	1.0	1.0
Fasting glucose[c]	Both	5.3 (1.9-11.5)	5.2 (1.5-18.2)	2.7 (0.89-8.4)
	Physician	4.2 (1.4-12.3)	3.8 (1.4-10.4)	2.3 (0.95-5.8)
	Patient	4.6 (1.4-20)	3.7 (1.6-8.7)	4.5 (2.0-10.0)
	Neither	1.0	1.0	1.0
Any test[c]	Both	5.5 (1.4-21.3)	5.5 (1.5-20.0)	2.6 (0.85-8.1)
	Physician	4.2 (1.4-12.5)	4.0 (1.4-11.1)	2.3 (0.93-5.6)
	Patient	5.4 (2.1-13.5)	4.4 (1.8-10.5)	4.8 (2.1-10.8)
	Neither	1.0	1.0	1.0

CI, confidence interval; *OGTT*, oral glucose tolerance test; *OR*, odds ratio.

[a] Assuming all patients who were lost to follow-up were screened; [b] Assuming all patients who were lost to follow-up were not screened; [c] Adjusted for covariates primigravida, macrosomia, and preterm delivery

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used was either a fasting glucose ($\chi^2 = 10.8$; $P < .05$) or the combination of any screening test was performed ($\chi^2 = 14.0$; $P < .05$; Table 1).

The multivariate logistic regression analyses for the primary outcome and the 2 significant secondary outcomes (fasting glucose and any screening test) that were adjusted for significant independent covariates are presented in the first column of Table 2. For the primary outcome, the groups (reminders sent to the physician, patient, or both) were associated significantly with screening. Patients and physicians who both received a reminder were 5.2 times likely (95% confidence interval [CI], 1.4-19.6) to be screened during the postpartum period with an OGTT; patients who received a reminder were 8.7 times likely to be screened (95% CI, 2.9-25.6), and patients whose physicians received the reminder were 8.4 times more likely to be screened (95% CI, 2.4-28.5), compared with no reminders received. When reminders were included in the logistic regression model, no other covariates re-

TABLE 3
Evaluation by subgroup with significant interaction

Outcome	**Effect**	**Reminder group**	**n**	**Screened (n)**	**OR**	**95% CI**
OGTT	Physician	Patient	157	91 (58.0%)	2.0	0.6-2.3
		No patient	66	21 (31.8%)	6.4	2.0-22.2
	Patient	Physician	112	65 (58.0%)	1.4	0.6-3.3
		No physician	111	47 (42.3%)	7.4	2.6-21.3
Fasting	Physician	Patient	157	112 (71.3%)	0.8	0.4-1.7
		No patient	66	36 (54.5%)	5.4	1.5-18.9
	Patient	Physician	112	77 (68.8%)	0.94	0.4-2.5
		No physician	111	71 (64.0%)	4.5	1.7-11.4
Any test	Physician	Patient	157	121 (77.1%)	0.8	0.4-1.7
		No patient	66	38 (57.6%)	4.8	1.4-16.1
	Patient	Physician	112	83 (74.1%)	1.1	0.4-2.8
		No physician	111	76 (68.5%)	5.4	2.1-13.9

CI, confidence interval; *OGTT*, oral glucose tolerance test; *OR*, odds ratio.

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mained associated independently with screening with an OGTT. For the secondary outcomes, similar results were found with both interventions, because physician intervention and patient intervention all increased the likelihood of screening (Table 2).

A sensitivity analysis was performed to evaluate the effect of patients and/or physicians who were lost to follow-up on the outcomes. Rates of screening were calculated with the assumption that all patients who were lost to follow-up were screened (sensitivity analysis 1) or alternatively not screened (sensitivity analysis 2; Table 2). There was some change in the point estimate and 95% CI for the primary outcome, but the results were unchanged for both sensitivity analyses. For the secondary outcomes, results from screening with fasting glucose and screening were not as robust. Sensitivity analysis 2 was not significant for the combination of the 2 interventions and the physician intervention.

We were unable to determine the physician effect of the intervention vs the patient effect of the intervention because the 2 interventions were not independent of each other; the effect of each intervention varied depending on whether a patient or physician intervention was received (a statistical interaction). Given the interaction of the 2 interventions, a subgroup analysis was performed to evaluate the effect of the patient and the physician intervention independently of the other intervention (Table 3). For the primary outcome, when no reminder was sent to the patient group, the physician reminder significantly increased screening (OR, 6.4; 95% CI, 2.0-22.2); when no reminder was sent to the physician, the patient reminder significantly increased screening (OR, 7.4; 95% CI, 2.6-21.3). However, the effect of the physician reminder was no longer significant when all patients received a reminder (OR, 2.0; 95% CI, 0.6-2.3). Similarly, the effect of the patient reminder was no longer significant when all the physicians received a reminder (OR, 1.4; 95% CI, 0.6-3.3).

COMMENT

We found that sending a postal reminder to the patient, the physician, or both greatly increased screening for diabetes mellitus with the CDA recommended screening test for patients with previous GDM, as compared with usual care.

Our study is the first randomized controlled trial to evaluate an intervention to increase screening in women with GDM. Four retrospective observational studies have been published.[12-14,20] Three of the studies report postpartum screening rates of 37-45% with either a fasting glucose test or an OGTT.[13,14,20] Two studies report postpartum screening rates specifically with an OGTT of 0-23%.[12,20] The rate of screening with the recommended OGTT in the usual care group of our study was higher than we had assumed, based on our previous work, but still very low at 14.3%.

One prospective cohort study has been published in which all women with GDM were provided laboratory requisitions at discharge from hospital; the case was followed by contact at home by a case-manager who could perform the test. This intervention led to an OGTT screening rate of 41%.[10] Our simple intervention of sending a postal reminder led to screening rates that ranged from 51.6-60.5% for a reminder sent to either patient, physician, or both in our population.

We had expected that, when a patient or physician received a reminder, the addition of a second type of reminder would increase screening further, because other studies had found that multiple interventions were usually more successful than single interventions.[18] A screening rate of approximately 60% for this test may be the highest that is achievable in this population and is the highest published screening rate at this time.

Despite our rigorous attempts to ensure that the intervention had been received and the patient was available for screening, we still had a large number of patients or physicians (12.9%) who were lost to follow-up. In 40% of the cases that were lost to follow-up, we were able to determine that either the patient or the physician had moved. However, a sensitivity analysis for the primary outcome (OGTT) did not change the overall results.

Performance of this study in 1 urban multicultural center with a predominantly white population who were highly educated may limit the generalizability of results because this population may be more inclined to participate in screening during the postpartum period when reminded. Group allocation in our study was by patient; therefore, a large number of patients who shared a family physician were excluded. We allocated patients as the unit of randomization to avoid contamination (ie, a physician would be more likely to screen all patients in the practice the same way).

In summary, evidence-based guidelines must be reinforced with evidence-based implementation strategies. Usual care continues to result in very low levels of screening for diabetes mellitus in the postpartum period, despite increasing recognition of the high risk in this population. Failure to do an OGTT in the postpartum period will miss at least 30% of the women who have diabetes mellitus. A simple, low-cost patient-specific intervention has been demonstrated to improve screening rates greatly. Care providers should consider implementing a structured approach to postpartum follow-up in women with GDM. However, even with a postal reminder to the patient, physician, or both, 40% of the women in our study still continue not to receive the best screening test. Further studies on screening barriers, the exploration of other methods of communicating screening recommendations, and the assurance of performance of screening for diabetes mellitus in this high-risk group are required. ■

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