Methods to Encourage the Use of Antenatal Corticosteroid Therapy for Fetal Maturation
A Randomized Controlled Trial

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Context Antenatal corticosteroids for fetal maturation have been underused, despite evidence for their benefits in cases of preterm birth.

Objective To evaluate dissemination strategies aimed at increasing appropriate use of this therapy.

Design and Setting Twenty-seven tertiary care institutions were randomly assigned to either usual dissemination of practice recommendations (n = 14) or usual dissemination plus an active, focused dissemination effort (n = 13).

Subjects Obstetricians and their preterm delivery cases at participating hospitals.

Intervention Recommendations by a National Institutes of Health (NIH) Consensus Conference held in late February–early March 1994 were disseminated in early May 1994. Usual dissemination was publication of the recommendations and endorsement by the American College of Obstetricians and Gynecologists. Active dissemination was a year-long educational effort led by an influential physician and a nurse coordinator at each facility, consisting of grand rounds, a chart reminder system, group discussion of case scenarios, monitoring, and feedback.

Main Outcome Measure Use or nonuse of antenatal corticosteroids was abstracted from medical records of eligible women delivering at the participating hospitals in the 12 months immediately prior to release of the NIH recommendations (average number of records abstracted, 130) and in the 12 months following their release (average number of records abstracted, 122).

Results Active dissemination significantly increased the odds of corticosteroid use after the conference. Use increased from 33.0% of eligible patients receiving corticosteroids to 57.6%, or by 75% over baseline, in usual dissemination hospitals. Use increased from 32.9% to 68.3%, or an 108% increase, in active dissemination hospitals. Use in- ter the conference. Use increased from 33.0% of eligible patients receiving corticoste- roids to 57.6%, or by 75% over baseline, in usual dissemination hospitals. Use in- creased from 32.9% to 68.3%, or an 108% increase, in active dissemination hospitals. Gestational age and maternal diagnosis affected use of the therapy in complex ways.

Conclusion An active, focused dissemination effort increased the effectiveness of usual dissemination methods when combined with key principles to change physician practices.

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steroids associated with publication of practice recommendations (usual dissemination) with those caused by an active, focused dissemination effort (active dissemination), in addition to the practice recommendations. The randomized trial addressed the 3 following questions:

1. Will publication of the NIH recommendations be associated with increased use of corticosteroid therapy? Consensus conference recommendations published by the NIH have rarely induced timely, widespread changes in physician practice. However, change can take place more quickly when professional societies endorse practice recommendations.10-11 The American College of Obstetricians and Gynecologists generally endorsed the NIH recommendations, which could speed their adoption.1

2. Will an active dissemination effort cause a greater increase in use of corticosteroids than that associated with the NIH recommendations alone? The randomized trial was a formal test of this question. We used important principles to speed adoption of the recommendation, based on a substantial body of research and tailored to the barriers obstetricians identified.10-12

3. How will characteristics of the individual case, specifically GA and maternal diagnosis, affect the use of the therapy? This question was exploratory. Because very low-GA cases had received the therapy least, we believed obstetricians would respond differentially to the recommendations based on GA. In addition, they were likely to respond differently to women presenting with preterm, premature rupture of membranes (PROM) compared with other maternal diagnoses. Although the consensus conference had endorsed the therapy in cases of PROM, the American College of Obstetricians and Gynecologists committee concluded that more research on risks and benefits was needed.1

METHODS
NIH Recommendations
The NIH Consensus Conference reviewed the evidence concerning efficacy of corticosteroids for preterm deliveries of different types.6-13 The panel recommended that all women at risk of premature delivery, between 24 and 34 weeks’ gestation, should receive the therapy, unless there are contraindications because of maternal disease. If PROM is diagnosed, the therapy is recommended for women of up to 32 weeks6 gestation, unless clinical chorioamnionitis is present. Two corticosteroids appear equally effective: 2 doses of 12-mg betamethasone intramuscularly 24 hours apart, or 4 doses of 6-mg dexamethasone given intramuscularly 12 hours apart. The therapy should be administered unless delivery is imminent.6

To understand the reasons for limited use of corticosteroids, we conducted interviews and focus groups with maternal-fetal medicine specialists, neonatologists, and obstetricians around the nation.12 The panel crafted its recommendations specifically to address the uncertainties and reservations practitioners voiced. For example, the recommendation for practice was fairly simple, because practitioners gave several reasons for delaying the administration of corticosteroids. Also, practitioners overestimated risks and underestimated benefits. The NIH recommendations began with the statement: “The benefits of antenatal administration of corticosteroids to fetuses at risk of preterm delivery vastly outweigh the potential risks.”6

Selection and Randomization of Hospitals
The design of the randomized trial is shown in FIGURE 1. To avoid diffusion of the active dissemination treatment to the control group, the unit of randomization and treatment was the hospital. The hospitals were all tertiary care facilities with neonatal intensive care units (NICUs), institutions most likely to adopt these NIH recommendations quickly. Of 30 hospitals invited, 27 participated. Criteria for participation included having at least 100 eligible cases in the baseline year, having no standing protocol, and participating in no other research in antenatal corticosteroids. Albert Einstein College of Medicine (AECOM) of Yeshiva University, New York, NY, recruited 8 affiliated hospitals and all participated. The National Perinatal Information Center (NPIC), Providence, RI, recruited 22 hospitals from its 1994 member network and 19 participated. One NPIC hospital never responded and 1 refused participation. Hospitals were then randomized, but before intervention started another NPIC hospital withdrew, precluding data collection.

The NPIC and AECOM conducted randomization separately for their member hospitals. We assigned hospitals by random number table either to the active dissemination (n = 13) or usual dissemination control (n = 14) group. National Perinatal Information Center hospitals all were located a substantial distance from each other, so diffusion of the intervention to control institutions was unlikely. Hospitals selected by AECOM were all in the New York area. However, cross-hospital diffusion of the intervention was unlikely because almost no practitioners overlapped across institutions, and residents were shared only by 2 institutions that were both fortuitously randomized to active dissemination. The study was not blinded because physicians in the active dissemination...
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dissemination condition were aware of the study, and the leadership of all hospitals (including the chairpersons of obstetrics and gynecology departments) were aware of the condition of assignment.

Treatment and Control Groups

The NIH Consensus Conference convened in late February 1994. The consensus conference final statement was released on May 27, 1994. The American College of Obstetricians and Gynecologists’ opinion statement on antenatal corticosteroids was mailed to its members in December 1994 and by the end of January 1995, NIH brochures outlining the conference recommendations had been mailed to medical care institutions, universities, medical societies, and obstetricians. In addition, JAMA published the NIH recommendations on February 1, 1995, and a second publication appeared in a special supplement to the July 1995 issue of the American Journal of Obstetrics and Gynecology on antenatal corticosteroids for fetal matura-
tion. These activities, the available research literature, various lecture formats, and word-of-mouth discussions constituted the way NIH recommendations are usually disseminated and were the way physicians in the control hospitals, the usual dissemination control group, received the information.

We exposed intervention hospitals to an active, focused dissemination effort, tailored to overcome barriers impeding the use of corticosteroids. Active dissemination began in spring 1995. Implementation at the 13 intervention hospitals was staggered from April through mid July 1995 to accommodate supervision of start-up and the scheduling of grand rounds by study investigators. Implementation consisted of 5 components designed to make use of research on adoption of medical practices. The components are as follows:

1. An influential physician and nurse coordinator at each hospital were recommended by the director of the department of obstetrics or by the director of maternal and fetal medicine, if appropriate. Influential physicians were maternal-fetal medicine specialists, perinatologists, or obstetricians who were willing to champion the NIH recommendations. They had influence with colleagues who managed cases that were considered at high risk of premature delivery. Obstetricians had expressed a need to consult a local expert, and we expected that they would influence practice in the same way that opinion leaders have done. Influential physicians facilitated the study’s active dissemination effort at treatment hospitals, in partnership with nurse coordinators.

2. A grand rounds lecture on antenatal corticosteroid therapy was given by a nationally respected expert. The grand rounds lecture emphasized that the majority of women giving birth prematurely should be treated with corticosteroids. Focus groups had revealed that the time interval before women received the therapy varied greatly for no apparent reason. The lecture also emphasized timely action to ensure that women received adequate doses. Those attending the grand rounds session received the consensus conference statement, key research articles and citations, and samples of a sticker prompt and chart reminder.

3. A chart reminder system was designed to prompt physicians to consider prescribing therapy on a timely basis. In prior research, reminders substantially increased the amount of a desired practice. Nurse coordinators inserted reminders in eligible charts as soon as possible after admission. The chart reminders were large and brightly colored. The outside of the flagged charts bore a brightly colored sticker concerning corticosteroid use.

4. Group discussions were led by the influential physicians. The hour-long, informal groups included the hospitals’ obstetricians and residents discussing 4 case scenarios in which corticosteroids might be administered, the ideal case of spontaneous preterm labor, a case of PROM, early GA and no prenatal care, and complicated pregnancy (maternal chronic hypertension and diet-controlled diabetes). The goals were to gain a consensus from the group on basic management strategy, to elicit reasons why corticosteroids would or would not be used, and to draw out differences in management strategy in accordance with the scenarios.

5. Monitoring of care provided feedback to physicians. Performance feedback has been found to be an effective way to change practice patterns. Nurse coordinators kept logs of preterm admissions and deliveries to determine whether charts had inserts in them and whether corticosteroids were given and when. Influential physicians received reports during the year following the conference outlining the extent of corticosteroid use (at months 6-7), extent to which chart reminders were inserted (at months 7-8), and the timing of corticosteroid administration (at months 8-9). Most reports were shared with colleagues.

Fidelity of Implementation

As is often the case in a decentralized effort, the treatment hospitals varied in the extent to which they implemented active dissemination. Across the 13 intervention hospitals, average attendance at the grand rounds was 63% (range, 33%-93%) of obstetricians managing high-risk deliveries. The proportion of chart reminders inserted in eligible records averaged 73%, and across intervention hospitals, they ranged from 40% to 93%. All institutions included the component of case scenario discussions, and all influential physicians and nurse coordinators responded to feedback on implementation.

Sampling of Records and Data Collection

For statistical power, our goal was to abstract an average of 162 medical charts per hospital per study year. The charts of 6798 eligible women were abstracted from the 27 institutions, 3516 in the baseline year and 3282 in the after-conference year. We abstracted data on the use of corticosteroids, the timing of their administration, and maternal and infant conditions. To measure hospital practices at baseline, we abstracted maternal medical records from the 12 months immediately before any consensus conference activity or publicity had
begun (March 1993-February 1994). Chart abstraction from the 12-month period following the conference began in April 1995 and ended in July 1996. To control for the staggered implementation schedule, record abstraction used the same after-conference time frame for active- and usual-dissemination hospitals in the same geographic regions.

Eligible cases included all women giving birth at 34 weeks’ GA or less, including cases of spontaneous preterm labor, PROM, and preterm delivery indicated because of medical conditions. It is important to note that in cases of suspected preterm deliveries, it is not always possible to know which women will deliver preterm. Therefore, some women who did not deliver preterm also received corticosteroids. However, we have no data on these patients, and the sampling frame did not include them.

The number of usable abstracts per hospital averaged 130 in the baseline year (range, 81-168) and 122 in the after-conference year (range, 73-170). We included all eligible cases from AECOM hospitals and sampled 81% of all eligible records from the often-larger NICP hospitals. Because we wanted to analyze responses to individual cases based on GA, we oversampled the comparatively rare births of neonates between the ages of 24 and 28 weeks’ GA. For hospitals with 162 cases or fewer in each year, we abstracted medical records of the entire population of preterm deliveries. For NICP hospitals with more than 162 cases, we abstracted the entire population of births of neonates whose GA was between 24 and 28 weeks; a random sample of other preterm deliveries was then included, up to 170 cases. Two hospitals had a large census of preterm deliveries; from these hospitals, we selected a simple random sample of neonates of all GAs. Hospital census varied by year, and, therefore, the oversampling had to vary. In the baseline year, 4 treatment and 4 control hospitals included the entire population of low GA cases (31% and 28%); in the after-conference year, 3 treatment hospitals and 5 control hospitals (23% and 36%) included all the low GA cases.

We trained medical data collectors to identify cases in a 2-stage process. To enumerate and sample cases, they first examined logs kept by hospital labor and delivery units. Then, they inspected the records and abstracted those that met criteria. They discarded cases at stage 2 for the following reasons: GA was outside study criteria; GA was not recorded; fetal death was verified on admission; record numbers were inaccurate; records could not be located; and no admission corresponded to delivery information. Based on the log enumeration, we discarded a median of 10.5% of records across hospitals. In 3 hospitals, the proportion of discarded cases exceeded 20%. These 3 hospitals had many cases that appeared eligible on labor and delivery logs, but the medical records listed GA older than 34 weeks or younger than 24 weeks. In these 3 hospitals, between 8% and 13% of the records could not be found.

**Analysis**

Corticosteroid administration was influenced both by factors at the patient level, such as maternal diagnosis, and by hospital-level factors, such as the historical rate of corticosteroid use and the hospital-wide dissemination efforts. Analysis addressed both levels because information is lost if either level is ignored. The physician level of analysis was not available to the study because a condition for hospitals’ participation was that individual physicians would not be studied. The primary analysis was based on a 2-level logistic regression model, with patients as the units of analysis at level 1 and hospitals at level 2.  

Patient-level variables included the study year (baseline vs after conference); corticosteroids received or not received (not received includes cases in which corticosteroids were ordered but not administered); GA between 24 and 28 weeks (24-28 weeks vs 33-34 weeks); GA between 29 and 32 weeks (29-32 weeks vs 33-34 weeks); and diagnosis of PROM (yes or no). Too few cases of indicated delivery appeared for meaningful separate analysis in the model; thus, the model contrasts spontaneous preterm labor and indicated delivery without PROM against deliveries with PROM. The hospital-level variable is treatment (active vs usual dissemination control). For practical reasons, we estimated a conservative model in which only coefficients for the main effects (study year, PROM, GA between 24-28 weeks and GA between 29-32 weeks) were allowed to vary randomly across hospitals. Nonsignificant main effects were included when they were involved in significant interactions, and only the significant interactions are included.

**RESULTS**

**Success of Randomization**

There were no baseline differences between intervention and control hospitals for the following characteristics: geographic region, median number of active obstetricians, births per hospital, NICU beds, percentage of Medicaid patients, race, PROM diagnosis, GA, and indicated deliveries. Hospital characteristics were generally the same in both the NICP and AECOM hospitals, so we do not report them separately. A difference between intervention and control cases in the frequency of abnormal fetal conditions or fetal distress was significant at the patient level ($\chi^2 = 10.73; P < .05$) due to the large sample size. It may be a chance effect, given the multiple comparisons between intervention and control institutions.

During the after-conference year, 2 differences in hospital case mix emerged between intervention and control institutions. Based on hospital census (not sampling), treatment hospitals had a larger proportion of the lowest GA cases in the after-conference year ($t = 3.36; P < .001$) because 3 control hospitals reduced their proportion of such cases, while 1 treatment hospital increased its proportion of these cases. In addition, in the after-conference year the average proportion of reported PROM cases increased in all hospitals but increased significantly more in treatment than in control hospitals ($t = 3.03; P < .006$). To examine whether these after-conference differences in PROM and GA would bias the tests of study hypotheses, we conducted 2 analyses. First, we established that there was no significant col-
linear relationship between corticosteroid use due to treatment and use due to either PROM or GA, by analysis of the level 2 parameter variation. If these variables had influenced the test of the dissemination treatment, collinearity would have been seen. Second, data were analyzed separately by various levels of GA and whether PROM was present (data not shown). Results are essentially the same as those reported herein. In other words, the change in case mix did not cause increased use of the therapy in the active dissemination group.

Effects of Dissemination Strategies

In the Table, we provide an overview of the percentage of use of corticosteroids by study year and treatment condition at both the patient and hospital levels of analysis. The 2-level logistic regression revealed a significant effect of study year (P<.01). Controlling for other variables in the model, the expected increase in the odds of corticosteroid use after the consensus conference (compared with baseline) is 3.16. In usual dissemination hospitals, use of corticosteroids increased 75% from baseline to after the conference. In the active dissemination hospitals, however, intervention gave a statistically significant “boost” to the effect of the after-conference study year. Active dissemination increased the odds of administering corticosteroids during the after-conference year by a factor of 1.63 (P<.01). In active dissemination hospitals, use of corticosteroids increased 108% from baseline to after the conference, more than one third again as much as in the control hospitals.

Hospitals showed extreme and statistically significant variation in corticosteroid use, which is not explained by the treatment effect. This variation is significant across hospitals in terms of increased use of corticosteroids due to the NIH recommendations (after conference vs baseline) increased use in PROM and increased use at various GAs. Across hospitals, the increase in the rate of corticosteroid use ranged from +5% to +62%. Some hospitals increased corticosteroid use minimally, while others changed their practices radically; some responded to patient characteristics in markedly different ways.

Effects of Patient Characteristics

Gestational age and the presence of PROM were associated both with baseline corticosteroid use and with increase in corticosteroid use following the conference. These relationships are shown in Figure 2, which also describes the indicated deliveries separately. In both the baseline and the after-conference years, patients with lower GA were significantly more likely to receive corticosteroids than those with higher GA. Compared with GA between 33 and 34 weeks, the baseline odds ratio was 4.48 for GA between 24 and 28 weeks and 2.95 for GA between 29 and 32 weeks (both P<.01). In addition, the increase in corticosteroid use during the after-conference year was significantly less for patients with GA between 24 and 28 weeks than for those with GA between 33 and 34 weeks (interaction of GA 24–28 weeks and study year, P<.01). Although at baseline use of the therapy was less likely in cases in which PROM was present than when it was not, during after-conference year it increased to a greater degree when PROM was present (PROM by study year interaction, P<.01).

Appropriateness of Practice Changes

The NIH panel stated that chorioamnionitis and imminent birth are contraindications for the therapy. In this data set, we could not assess whether chorioamnionitis was diagnosed before or after corticosteroids were administered. However, chorioamnionitis was present in

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**Table. Percentage of Patients Receiving Antenatal Corticosteroids: Baseline, After Conference, and Gain Across Study Years**

<table>
<thead>
<tr>
<th>Patient-level results†</th>
<th>Usual Dissemination</th>
<th>Active Dissemination</th>
<th>Between-Group Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deliveries baseline</td>
<td>33.0</td>
<td>32.9</td>
<td>+33‡</td>
</tr>
<tr>
<td>Deliveries (after conference)</td>
<td>57.6</td>
<td>68.3</td>
<td></td>
</tr>
<tr>
<td>Increase from baseline to after conference</td>
<td>75</td>
<td>108</td>
<td></td>
</tr>
</tbody>
</table>

| Hospital-level results‡ | Mean deliveries (baseline) | 34.2 | 32.6 | +45‡ |
|                        | Mean deliveries (after conference) | 57.4 | 69.4 |     |
|                        | Increase from baseline to after conference | 68 | 113 |     |

*All values are presented as percentages.
†Patient-level percentages differ from hospital-level percentages because group analysis compares hospital mean percentages.
‡P<.01.

**Figure 2. Corticosteroid Use by Gestational Age and Delivery Type at Baseline and After-Conference Year**

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13.9% of patients receiving therapy in the year before the consensus conference and in 13.4% in the after-conference year. There were no differences between usual- and active-dissemination hospitals in the proportion receiving corticosteroids. “Imminent delivery” was not defined by the panel. However, significantly more deliveries (3.0%) occurred within 2 hours of first corticosteroid use in the after-conference year, compared with 1.8% at baseline (t = 2.36; P < .05).

**COMMENT**

**Increase in Corticosteroid Use After Release of the NIH Recommendations**

In the 12 months after the consensus conference, use of the therapy increased dramatically among both active- and usual-dissemination hospitals. Few studies of practice recommendations have examined the appropriateness of change.22 Although our conclusions are preliminary, it appears that inappropriate use increased only in the case of imminent delivery, affecting an additional 1.2% of cases in which the therapy was given, a level that is more than counterbalanced by the benefits accruing to neonates. In both time periods, questions about potentially inappropriate use of corticosteroids were present in about 16% of cases, and in most of these, it is likely that their use was appropriate at the time they were given.

The effectiveness of the NIH recommendations is consistent with other research identifying the forces affecting the adoption of practice guidelines, ie, endorsement by the American College of Obstetricians and Gynecologists, a fairly simple recommendation, and absence of alternative or competing therapies.17,21 By studying tertiary care institutions, the study probably captured the actions of those who would be the first to adopt the NIH recommendations.23 This is both a strength, in that the study captured the change as it occurred, and a limitation, since less-specialized hospitals were not represented. However, we required a high volume of preterm deliveries for statistical power, which was the deciding factor.

**Effect of Active Dissemination**

Active dissemination, at a minimum, hastened adoption of the therapy. An additional 170 patients, or 13 per hospital, received corticosteroids in the after-conference year over and above the number of patients who received it at usual-dissemination hospitals. Given the substantial reduction in morbidity and mortality, plus the cost savings per treated neonate, these results are not trivial. Moreover, the effort involved in this educational intervention was relatively low compared with the labor-intensive strategy of one-on-one academic detailing.10,24,25 Few studies of practice guidelines have analyzed the costs and benefits of dissemination.21 In actuality, the cost of active dissemination was borne by the study and not by the participating hospitals. However, if the dissemination costs were borne by the hospitals, the costs would vary substantially based on issues such as whether the grand rounds speaker was an in-house expert or one flown in from outside, whether a nurse coordinator could add the intervention tasks to those currently performed, whether additional staff needed to be hired, and whether the influential physician received payment for assuming this role or whether this was simply one of the many functions performed by a department chair or division chief. Most important is whether one assumes additional costs for the practitioner’s time to attend educational sessions. Using various assumptions, the incremental cost of active dissemination could vary from $1000 to $16 000 per hospital in the first year. If these costs were spread over the additional 13 treated neonates in the first year, the incremental cost per treated infant would be between $77 and $1231, far less than the $3000 savings per treated neonate, according to the consensus conference.9 Since the cost of corticosteroid treatment is low, about $7, we believe active dissemination would substantially reduce costs relating to the care of the neonates.

Findings are mixed concerning the effectiveness of educational strategies. They were probably effective in the present study because it addressed specific barriers and because the overall climate favored a change.10-12 As a model for intervention, the active dissemination strategy has certain limitations. As in many dissemination studies, intervention is a complex package; additional research is needed to identify the “active ingredients” to change medical practices. Also, effectiveness has not been determined for hospitals implementing this strategy by themselves, without study oversight.

**Individual Patient Factors**

These findings highlight the importance of a 2-level analysis to preserve information about factors associated with change. Prior studies of practice guidelines generally analyze at the individual level or the organizational level, but not both.17,18 We did not predict that cases of PROM would see even greater increases in use of the therapy than other maternal diagnoses nor did we predict the high use, even at baseline, among very low-GA infants. These findings will require confirmation in future studies. However, we can speculate about the reasons. First, the study practitioners are located at tertiary care institutions, where it is likely that they have resolved these issues more rapidly than other institutions. Second, delivery was rarely imminent when PROM was diagnosed, but it was more commonly imminent among the women in spontaneous preterm labor. The timing of delivery in PROM cases is therefore under the obstetrician’s control to a greater degree, and the therapy could be appropriate for a higher percentage of cases. Finally, the high rate of corticosteroid use in very low-GA infants may be attributable to the progress seen in the outcomes of these infants. In the past, obstetricians may have questioned whether such infants would survive, and therefore did not treat them. With new technology to increase their survival, the decision to treat may be more common, along with greater awareness of the benefits of corticosteroids.

**Unexplained Hospital-Level Variation**

Although the treatment variable explained some of the hospital-level variation, there remain important differences among hospitals in both their initial...
use of corticosteroids and their responses to the NIH recommendations. Further work is needed to explain why hospitals differed so radically in their response to NIH recommendations. These differences in response to practice guidelines have occurred in other studies, and remain unexplained. Site-level differences are consistent with current understanding of corticosteroid therapy, the use of which varies markedly by institution. Not only did the rate of corticosteroid use vary initially, as noted in other studies, but institutions also varied in terms of their response to the recommended change.

CONCLUSIONS

The year after the NIH Consensus Conference on Antenatal Corticosteroid Therapy saw a marked change toward increased use of the therapy. An active dissemination effort significantly increased adoption of the NIH recommendations, over and above the effects of the usual consensus conference dissemination methods. We hypothesize that this occurred because conditions were favorable for adoption of the NIH recommendations and because active dissemination was tailored to concerns of obstetricians at the study institutions.

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