Postconception Menses Induction Using Prostaglandin Vaginal Suppositories

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Vaginal suppositories containing 15 methyl prostaglandin $F_{2\alpha}$ methyl ester in a high-melt base were administered to 60 women desiring early pregnancy interruption who were no more than 56 days' (eight weeks) pregnant as calculated from the first day of the last regular menstrual period (LMP). The purpose of this study was to evaluate the safety, efficacy, and patient acceptability of this mode of noninvasive early abortion. Some factors evaluated during the study included the time interval from insertion of the suppository to the onset of cramping and bleeding. Also measured were immediate and delayed blood loss, nausea, vomiting, and diarrhea. Of the 60 patients entered into the study, 55 procedures have been judged as successful by the prospective criteria set forth in the protocol. There were no deaths or serious complications. Four patients required hospitalization and follow-up dilatation and curettage (D&C). One patient withdrew from the study after receiving a suppository and subsequently delivered a preterm infant. ***(Obstet Gynecol 65:682, 1985)***

Abortion is a widely practiced intervention measure in the United States. Based on several abortion surveillance reports, it is estimated that 1,500,000 such procedures will be performed in the United States in 1984.[1,2] Additionally, it is well established that abortion complications and gestational age are directly related, ie, as pregnancy advances, complications increase.[3-5] Given these circumstances, it is understandable that efforts are being directed towards developing earlier and thus safer abortion techniques.

Use of the naturally occurring prostaglandins E and $F_{2\alpha}$ to induce abortion, dates back nearly 15 years.[6-8] However, because of the rapidity with which these compounds are degradated by the enzyme prostaglandin, 15 dehydrogenase, they must be administered by continuous intravenous infusion or by repeated intramuscular or intravaginal methods. The introduction of a methyl group in the 15 position on the prostaglandin $F_{2\alpha}$ molecule results in its slower inactivation.

A protocol was developed to evaluate the safety, efficacy, and patient acceptability of postconceptional menses induction in very early pregnancy using (15S)-15-methyl ester prostaglandin $F_{2\alpha}$ vaginal suppositories.* The potential advantages of a noninvasive early abortion technique are obvious—simplicity of administration, avoidance of uterine instrumentation, and increased cost efficiency. An earlier study using this technique in a smaller group of patients reported a success rate of only 53%.[9] Presented are the results of 60 such patients who participated in this multicentered study.

Materials and Methods

Two suppository formulations were used: 3.0 mg of (15S)-15 methyl prostaglandin $F_{2\alpha}$ methyl ester in 2.2 g high-melt base, and 1 mg of (15-S)-15 methyl prostaglandin $F_{2\alpha}$ methyl ester in 800 mg high-melt base. Of the 60 patients studied, the first nine received a single 3-mg suppository and the remaining 51 received an initial 1-mg suppository followed three hours later by a 3-mg suppository.

Eligible patients included those in good health who were voluntarily seeking pregnancy interruption and were no more than 56 days' (eight weeks) pregnant as calculated from the first day of the last regular menstrual period. Establishing the existence of pregnancy this early is now practical given the ability to accurately measure human chorionic gonadotropin activity.[10,11] Additionally, uterine size was estimated by bimanual pelvic examination.

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Ultrasound was not used routinely. All patients were volunteers who provided informed written consent and were legally approved for pregnancy termination as applicable in the state of Tennessee. The investigational status of this drug was made known to all participants. Patients were excluded if they possessed any of the following: signs or symptoms of threatened or inevitable abortion, previous attempts to terminate the current pregnancy, clinical evidence of cervical incompetency, active or suspected gynecologic disease including inflammatory processes, any recognizable uterine anomalies, cardiac, renal or hepatic diseases, or pulmonary disease including asthma.

Patients were admitted to the hospital, at which time a full medical history was obtained, and physical and pelvic examinations were performed. Laboratory analyses were obtained on admission, ten hours after admission and at the two-week follow-up examination. Two sets of analyses were obtained. Those conducted by the investigators were as follows: hemoglobin, hematocrit, white blood count, differential platelet count, urine analysis including specific gravity, pH, acetone, glucose, protein, and microscopic analysis. The analyses done by the Upjohn laboratory were for bilirubin (direct and indirect), serum glutamic oxaloacetic transaminase, serum glutamic pyruvic transaminase, alkaline phosphatase, creatinine, blood urea nitrogen, electrolytes (including sodium, potassium, and chloride), and blood glucose.

The first nine patients were part of a single 3-mg suppository protocol. In the remaining 51 patients, the two-suppository protocol was used. It appeared that the two-suppository protocol allowed for a "preinduction ripening" effect on the cervix. All patients in both studies were administered pretreatment antiemetics in the form of diazepam* 10 mg and the antidiarrhea medication diphenoxylate hydrochloride,† one tablet by mouth, 30 to 60 minutes before the first suppository insertion.

Temperature, radial pulse, respiration, and recumbent blood pressure were taken and recorded initially, and then every hour thereafter for the remainder of the ten-hour observation period. The prostaglandin suppository was administered by digital separation of the labia and insertion high into the vagina in the region of the posterior fornix. The patient then was required to maintain the supine position for the ensuing 60 minutes; thereafter, she could ambulate as desired. For the two-suppository protocol, the second 3-mg suppository was inserted three hours after the first and again the patient was required to maintain the supine position for 60 minutes. The patient was then kept in the hospital under observation for at least ten hours, but was free to ambulate. Blood loss was estimated by measuring the dimensions on a sanitary napkin, using 10 mL of blood as a standard.

* Valium, Roache Laboratory, Nutley, NJ.
† Lomotil, Searle Pharmaceutical, Chicago, IL.

Results

For the purpose of this study, the criteria for a therapeutic success included evidence of sustained uterine bleeding characteristic of menses accompanied by significant and sustained decrease in the human chorionic gonadotropin (hCG) level after a period of two weeks. In this study, 55 of 60 patients achieved this end (91.6%). Four patients subsequently required suction dilation and evacuation—two because of positive hCG levels two weeks after the procedure and two because of continued vaginal bleeding at four weeks. The reason for the failures was not readily apparent. Two of the patients were in the single-suppository protocol, and the other two were in the two-suppository protocol. The average length of pregnancy for these patients who failed was slightly longer—46.2 days compared with 45.6 days for the entire study. There were no ectopic pregnancies. Most interestingly, a fifth patient whose hCG level remained elevated at two weeks opted to continue her pregnancy, which concluded with the vaginal delivery of a 1400-g male infant at 34 weeks' gestation. There was no evidence of teratogenesis, and his development thus far remains normal.

Of the 60 patients, 58 were black and two were white. The patients ranged in age from 15 to 31 years (mean 23.06 ± 4.2), in weight from 45 to 106.2 kg (mean 61.3 ± 12.2), and in height from 147.3 to 182.8 cm (mean 163.5 ± 6.8 cm). Gestational age ranged from 35 to 56 days (mean 45.6 ± 7.2). Originally the study was designed to accept patients who were no more than 49 days' (seven weeks') pregnant; however, after one patient was entered into the study, it was subsequently learned that her LMP had been incorrectly reported by one week, thus explaining the 56 days' gestational age. All other patients were 49 days' pregnant or less. The gravidity including the index pregnancy ranged from one to eight (mean 2.5 ± 1.62). Thirty-one patients (51.6%) were nulliparous. The hCG levels at entry into this study ranged from 16,000 to 65,000 mIU/mL (mean 22,634 ± 18,804).

Figure 1 summarizes the frequency of successful menses induction with respect to the time required. Because gestations were so early (all 49 days or less with the one exception cited above), the passage of identifiable fetal tissue was not a usable endpoint. In all cases, uterine contractions preceded uterine bleeding. The insertion to contraction time from the first

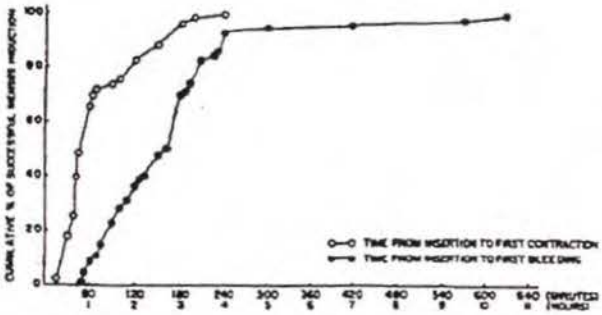


Figure 1. Time from first suppository insertion to onset of cramping and bleeding.

suppository ranged from 15 to 240 minutes (four hours), the insertion to bleeding time ranged from 55 to 630 minutes (ten hours and 30 minutes). All patients had begun to have contractions by four hours after suppository insertion, and 93.3% had begun to bleed by then.

There were no deaths or serious side effects. However, the problems with diarrhea and vomiting were frequent despite the use of diphenoxylate hydrochloride and diazepam in all patients. Thirty-seven of the 60 patients (61%) had vomiting and or diarrhea. No patients had vomiting without diarrhea, although the reverse was true. The events of diarrhea and vomiting usually occurred within 30 minutes of each other, and these symptoms usually had their onset at approximately two hours after insertion of the first suppository. Three patients had four episodes of vomiting and one patient had three episodes of diarrhea (Table 1). Over 50% of patients who had either of these side effects only had a single episode. The average number of episodes of diarrhea and vomiting was 1.48 and 1.57, respectively. No patients developed any obvious dehydration or fluid and electrolyte imbalance as the results of these two side effects.

Blood loss was evaluated in two contexts: the estimated blood loss during the ten-hour in-hospital observation period, and the time at which the vaginal bleeding ceased during the 14-day postprocedural observation period. The estimated blood loss during the ten-hour observation period ranged from 35 to 250 mL

Table 1. Prostaglandin Suppository Side Effects

Vomiting		Diarrhea	
No. of episodes	No. of patients	No. of episodes	No. of patients
1	15	1	15
2	3	2	11
4	3	3	1

Average number of vomiting episodes, 1.57. Average number of diarrhea episodes, 1.48.

Table 2. Outcome Correlations

Independent variables	Dependent variables*		
	Insertion to contraction interval	Insertion to bleeding interval	In-hospital blood loss (10 h)
Age		Neg	
Abortions	Neg	Pos	Pos
Parity		Pos	Pos
Weeks' pregnant		Neg	

Neg = negative; Pos = positive.
* Significance level $P < .05$.

(mean 64.1 ± 31.43). The time frame in which va... bleeding ceased in the 14-day postprocedure obs... tion ranged from five to greater than 14 days. E... percent had stopped their bleeding by the 14th d... Five patients failed to return for followup. No pati... required blood transfusions, and there was no sig... cant decrease in the hematocrit level.

Discussion

To more objectively evaluate safety, efficacy, and p... tient acceptability, five dependent and four indepe... dent variables were identified (Table 2). The analy... applied was that of multiple regression analysis usin... the statistical package for the social sciences. As stat... earlier, the 60 patients were comprised of two groups... In nine patients, a single vaginal suppository was use... and in the remaining 51, the two-suppository regimen... was applied. The variable analyses were run separately... on the nine-patient group, the 51-patient group, and... then the 60-patient group as single groups. The only... trend noted in these separate analyses was that the... nine single-suppository cases showed a slightly longer... time interval from suppository insertion to uterine... bleeding. However, this difference was not statistically significant; therefore, the following discussion relates to the outcome of all 60 patients. Table 2 shows the results of five dependent and four independent variables. The dependent variable, insertion to first vaginal bleeding, revealed the largest number of significant correlations. Some of these warrant comment.

Age showed a negative correlation. Hence, the younger the patient the longer the time interval from suppository insertion to first vaginal bleeding. Both previous abortion (spontaneous and induced) and parity showed a positive correlation. The later the gestation (weeks' pregnant) the shorter the time interval from suppository insertion to first vaginal bleeding.

The correlation for insertion to contraction time was negative for the number of previous abortions that a

patient had had. This would suggest that previous abortions in some way make the uterus more sensitive to the onset of contractions.

Estimated blood loss during the ten-hour in-hospital observation period showed a positive correlation for both the number of previous abortions and parity, whereas the total estimated blood loss over a two-week period was negative for parity. This finding would imply that early blood loss was lower in patients of low parity but higher for them over the later postabortal period. Also, delayed blood loss increased with advancing gestational age, an expected finding.

This study demonstrates that postconceptional menses induction in early human pregnancy can be achieved with vaginally administered prostaglandins. Further, the current findings and observations now allow some expectations with respect to drug response by patients. This procedure appears to be safe, as there were no deaths or major complications. Hence, two of the objectives of the study, efficacy and safety, seem satisfied. All patients except one stated that they probably would again undergo the procedure if necessary; however, most found the vomiting and diarrhea objectionable. Hence, the issue of patient acceptability remains less clear and must await further investigation.

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Development of Community-Based Health Services For Adolescents at Risk for Sociomedical Problems

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Abstract—Community-based service and training programs have been advocated as important for improving access to medical care for the poor as well as enhancing the ambulatory training setting for residents and medical students. In 1981 the Robert Wood Johnson Foundation provided funds to 20 teaching hospitals to support community-based, comprehensive health services to high-risk young people, that is, young people living in communities with high rates of sociomedical problems, such as adolescent pregnancy, drug abuse, alcohol abuse, accidents, homicide, suicide, and depression. In this article, the authors describe the experiences of these institutions in establishing off-campus clinics, concluding that high-risk adolescents need additional services and that teaching hospitals and communities can collaborate to provide these comprehensive services. They discuss issues of maintaining services after foundation grants end and the impact of recent financial restraints on continued support from teaching hospitals for off-campus activities.

Teaching hospitals serve large numbers of uninsured, poor patients, many of whom are young people seeking care for violence-related injuries, pregnancies, sexually transmitted diseases, substance abuse problems, and family planning services. Typically, the teaching hospital has provided this care through a variety of resident-staffed, campus-based clinics.

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In 1981, national health statistics revealed that young people between the ages of 15 and 24 comprised the only age group in the United States with a higher mortality rate in 1979 than in 1960, 7.5 percent higher (1). Moreover, large numbers of young people suffered from serious, if nonfatal, health and health-related problems, such as sexually transmitted diseases, unplanned pregnancies, alcohol and drug-related problems, episodes of violence, and mental illness (Table 1). The severity of these problems is compounded because many young people suffer from several problems simultaneously (2).

In the opinion of the authors, the U.S. health care system has not responded well to young patients with multiple problems.

TABLE 1

Selected Mortality Rates Per 100,000 Resident Population Between Ages 15 and 24 Years in the United States, 1960–1980

Deaths	1960	1970	1980
All deaths	106.3	127.7	115.4
Motor vehicle accident deaths	38.0	47.2	44.8
Homicide deaths	5.9	11.7	15.6
Suicides	5.2	8.8	12.3

Source: Reference 1.

Few health care providers are trained in adolescent health care. Available care, especially for low-income young people, tends to be fragmented and offered at disparate clinic sites. Moreover, young people tend to delay treatment because of difficulties in access and a desire to avoid dealing with complex institutions.

In 1981 sharp reductions in federal support for health services were proposed. The extent of these proposed reductions led to the conclusion that many clinics serving youth and offering services in family planning, mental health, and sexually transmitted diseases would close. In response to the health problems of high-risk adolescents and to difficulties in their access to health care, the Robert Wood Johnson Foundation funded a $12 million national demonstration program for improving health services and health outcomes for high-risk young people. The program involves grants to 20 teaching hospitals that, in partnership with public and private agencies, are providing community-based, comprehensive services to young people between 15 and 24 years of age. The demonstration is called the Program to Consolidate Health Services for High-Risk Young People (3).

Objectives and Rationale

The program has one ultimate goal—to improve the health of the target population. The program's four objectives reflect different approaches to achieving the goal: first, and most important, to increase services to high-risk youth; second, to train health providers in the care of young people; third, to consolidate health services into one-stop comprehensive care centers; and fourth, to secure long-term financial support for program projects.

The chief program objective—increasing health services for high-risk youth—reflected the Johnson Foundation's concern that certain health problems would not be addressed unless health services continued and expanded. The program protocol requires that program-supported services be comprehensive and community-based and include prevention as well as treatment services.

As its second objective, the program seeks to increase and improve health care for high-risk adolescents by training health professionals in the care of high-risk youth. Perhaps because adolescents and young adults have been perceived by the medical community as generally healthy, most health professionals have not received training in adolescent development and pathology (4, 5). Moreover, specialized training in adolescent medicine is a relatively recent phenomenon. Although adolescent units in hospitals first opened in the 1960s, they are still uncommon. And by the end of the 1970s, despite the growth of adolescent medicine divisions, few providers had received specialized training in adolescent health. Thus, the program seeks to enhance adolescent medicine by supporting adolescent medicine fellowships, facilitating community-based training for health care students, and encouraging continuing education for clinic staffs and community providers in the care of high-risk youth.

The third objective of the program, consolidation of services, reflects the services integration concept, which gained attention during the 1970s. Early in that

decade there was a growing awareness among health providers that the federal grants process had encouraged fragmentation of health services (6). Those involved in developing the high-risk young people's program judged that adolescents at risk for multiple problems would be unlikely to receive care if they had to seek treatment from multiple sources. It seemed that comprehensive services delivered at a single site was a better way to assure care for this population.

In 1981 consolidation also seemed to be an appropriate response to reduced funding for categorical services, such as family planning or maternal and child health care, that might force community clinics used by high-risk youth to close or cut back their services. By offering grant support to institutions that would cooperate in maintaining services, the program sought to demonstrate that needed services could be maintained in an era of retrenchment.

The fourth objective, securing long-term support for the projects, reflected a desire of the program developers that consolidated health services would continue beyond the end of the grant period. Because many effective and useful projects wither when grant support is withdrawn, the program required that long-term financial planning be a priority for each project.

In the program, teaching hospitals are the primary sponsors and lead agencies in organizing and developing clinics for adolescents. To be eligible for the program, teaching hospitals were required to identify community agencies, such as health departments, neighborhood health centers, schools, and juvenile justice agencies, that could serve as cosponsors in planning and implementing projects.

Teaching hospitals were selected as the primary sponsors for several reasons. A number of teaching hospitals have assumed a major role in providing care to the poor, especially through extensive outpatient departments. Moreover, teaching hospitals educate medical residents, nurse trainees, and other health professionals who could be involved in another major objective of the program—training health specialists in the care of high-risk youth.

In deference to their tertiary care function as well as education and research responsibilities, teaching hospitals have tended to avoid extended commitments to community-based care. During the 1960s and 1970s, however, a number of teaching hospitals broadened their ambulatory care and community commitments (7). By sponsoring activities such as neighborhood health centers, area health education centers, and children and youth programs, many teaching hospitals formed new relationships with community organizations and assumed new responsibilities for local community health. Some hospitals served high-risk youth through federal and state-supported categorical programs, such as family planning services and adolescent obstetrical clinics.

Although the extent of off-campus service and educational efforts has not been documented, in 1980 the Association of Academic Health Centers (AAHC) estimated that between 5 and 10 percent of medical education occurred in the community and reported that "this extent is considerably greater than it was 15–20 years ago" (8).

Recent developments in general pediatric residencies, with their greater emphasis on ambulatory and community-based activities, encouraged teaching hospitals to assume increased obligations to nearby adolescent populations. The focus of these residencies on primary care and prevention services is consistent with the priorities of the program for high-risk

young people. The concurrent development of divisions of adolescent medicine within the pediatric departments of many medical schools created a reservoir of specialized knowledge applicable to services for high-risk youth.

In the program, community-based organizations join teaching hospitals as cosponsors and as active partners in planning and implementing projects.

Several factors fostered collaboration between community cosponsors and teaching hospitals. First, in some communities both teaching hospitals and community agencies sponsored categorical services for young people—family planning, maternal and child health services, alcohol and drug treatment, and sexually transmitted disease services. Thus, teaching hospitals and community agencies could eliminate duplicate services or combine services to establish consolidated, comprehensive clinics. Grant support for the consolidated program would encourage sponsors and cosponsors to reduce the number of clinics while extending the availability of services.

Although some community organizations, particularly neighborhood health centers, had reported problems in working with teaching hospitals in the late 1960s, by the late 1970s many of these difficulties had been resolved. A number of neighborhood health centers had been established with support and encouragement from academic health centers, and many teaching hospitals offered staff privileges to health center physicians. Public and private community health agencies had referral relationships with medical center staffs, and training institutions allowed medical residents and others to work in community settings.

Participants and Activities

When the program was announced in July 1981, persons at 142 teaching hospitals expressed formal interest in applying for grants. Subsequently, 91 submitted complete applications, 30 were selected for site visits, and 20 received grants. Grantees are located in most sections of the United States.

Each grantee received approximately $600,000 for a four-year period. Grantees were selected on the basis of eligibility criteria and selection criteria. Eligibility requirements stipulated that an applicant must: (*a*) be a teaching hospital affiliated with a medical school and a member of the Council of Teaching Hospitals of the Association of American Medical Colleges, (*b*) report at least 5,000 outpatient visits by young people between the ages of 15 and 24 annually, (*c*) plan to provide services in an area where the incidences of eight major health problems (sexually transmitted diseases, teenage pregnancy, alcohol abuse, drug abuse, accidents, homicides, suicides and mental illness) are above the national rates, (*d*) have as cosponsors public and private agencies that serve high-risk youth, (*e*) be willing to provide services without regard to race or income, (*f*) be willing to participate in an independent evaluation designed to measure success in achieving the program's objectives, and be endorsed by the hospital director, the clinical department providing services, and the chief executive officers of the community agencies involved.

In addition to meeting eligibility criteria, applicants had to meet selection criteria. Applicants had to demonstrate great need for care as measured by the number of young people to be served and by the severity and incidence of health problems affecting young people in the proposed target area, to show strong promise of successfully consolidating services, and to show a strong likelihood of securing long-term support.

Program staff members and members

of the program's national advisory committee reviewed the grant applications. Applicants meeting eligibility criteria were visited by advisory committee members and program consultants who assessed the applicants and their proposed projects in terms of the selection criteria. Based on reports from the site visit teams, the national advisory committee recommended institutions for funding to the Johnson Foundation.

All program applicants were required to be members of the Council of Teaching Hospitals (COTH), which includes about 35 percent of the nation's teaching hospitals. Twelve of the grantee hospitals are publicly owned, and eight are private (60 percent and 40 percent respectively), a distribution that is the reverse of that of the COTH membership (38 percent publicly owned and 62 percent privately owned). In terms of bedsize and occupancy rates, the publicly owned grantees are similar to total COTH membership. The average number of beds at the privately owned grantees is 21 percent larger than at COTH privately owned hospitals (9).

In 1981 the publicly owned grantees provided relatively more charity and bad-debt care to the poor than publicly owned COTH members in general, 23 percent compared with 18 percent, as measured by percentage of full hospital charges. The proportions of Medicaid patients were similar, 21 percent and 20 percent respectively.* The privately owned grantees reported the same proportion of charity and bad-debt care, 4 percent, as did the privately owned COTH hospitals, 5 percent. But the privately owned grantees provided much more of their care to Medicaid patients than the privately owned COTH members, 18 percent compared with 13 percent. Both the publicly and privately owned grantees provided substantially more outpatient visits than did COTH members in general and also had more outpatient visits per inpatient day.

In terms of community-based or community-oriented service, five grantee hospitals had working arrangements with neighborhood health centers and community mental health centers and sponsored maternal and child health and other community services. In contrast, two institutions had no reported record of serving patients outside their institutional walls. Thirteen reported two or three community-based service or training activities.

The pediatric departments at 18 of the 20 grantee hospitals have the main responsibility for the at-risk youth projects. At one institution, the psychiatry department directs the project; at another, the director of student and employee health is project director.

The hospitals have a variety of relationships with academic medical centers. Of the publicly owned hospitals, five are owned by the universities, five have major teaching affiliation agreements with academic medical centers, and two have limited teaching affiliations. Of the eight privately owned grantee hospitals, two are owned by universities, five have major teaching affiliations, and one has a limited affiliation.

The relationship between the teaching hospital and its medical school establishes priorities for the sponsoring clinical department and the project director and, in turn, influences how the program is implemented at various sites. At university-owned teaching hospitals and other hospitals with particularly close ties to medical schools, teaching and research missions are often given priority over

* Personal communication, Judith Feder, Ph.D., and Jack Hadley, Ph.D., co-directors, Center for Health Policy Studies, Georgetown University, Washington, D.C., January 1985.

clinical services. At institutions where clinical service is a primary emphasis, the service objective of the at-risk youth program may create fewer problems.

The 20 grantees have established relationships with 54 community cosponsors. Four projects have five or more cosponsors, 10 have between two and four cosponsors, and six have a single cosponsor. Together the sponsors and cosponsors support 56 clinics for high-risk youth: seven are hospital based; 49 are community based. As reported in Table 2, neighborhood health centers are the most numerous cosponsors, closely followed by public health departments. Only three cosponsoring institutions withdrew during the first three years of the program. Although, in most cases, the grantee hospitals initiated efforts to persuade community agencies to join in planning services for high-risk youth, in four communities cosponsor agencies persuaded local teaching hospitals to submit the grant applications.

By June 30, 1984, all projects had experienced at least two years of program development; approximately half the projects began January 1, 1982, and half began July 1, 1982. During this period, the projects reported 174,521 patient visits at 56 service sites.

The patients who visited the program-sponsored clinics were predominantly between the ages of 15 and 19 (64 percent); 15 percent were 10 to 14, and 15 percent were 20 to 24. The patient population was primarily female (74 percent). Race was reported for approximately half of the patient visits, and the racial composition of these patients was 55 percent black, 31 percent white, and 14 percent Hispanic.

Because a program objective is to provide comprehensive services, all the sites except one offer comprehensive services. The site that is the exception is a venereal disease clinic that serves a large number of young men and offers mental health evaluation and limited counseling and screening and referral for other health problems. In seven instances, comprehensive health services are offered at sites where other youth-oriented programs are available, such as employment counseling, job training, and recreation.

Through the projects, pediatric faculty have undertaken a variety of training efforts in adolescent medicine, and all have begun at least two training activities. By July 1, 1984, 21 adolescent medicine fellows had been supported by high-risk youth grant funds; and 498 house officers, primarily pediatric residents, had participated in project-related activities during one- and two-month rotations. Graduate students, medical and nursing students, psychologists, and social workers have trained in adolescent health care through the program-sponsored clinics. Staff members at four grantee hospitals have prepared intensive workshops on the problems of high-risk youth for community providers.

Faculty members have also organized in-service training in the care of high-risk

TABLE 2

Numbers and Types of Community Cosponsors of Clinics for High-Risk Youth Participating in the Program to Consolidate Health Services for High-Risk Young People, 1981 and 1984

Cosponsors	1981	1984
Neighborhood health centers	14	14
Public health departments*	12	12
Nonprofit community agencies	9	9
Hospitals	7	6
Public schools	5	4
Health sciences centers	2	2
State departments other than health	2	1
Federal agencies	1	1
Indian tribes	1	1
Courts	1	1
Total	54	51

* Includes two state health departments.

youth for clinic staff-members, typically through lecture sessions and weekly case conferences. Cosponsors, which generally provide clinic space as well as support staff for services to high-risk youth, have stated that training is one of the immediate and tangible benefits from participating in the program. Moreover, clinics have been able to sustain or expand services for high-risk youth because faculty members and residents are made available to the clinics through grant support.

Discussion

The experience of the participating institutions suggests that the Johnson Foundation's rationale for the program was generally well founded. Many high-risk adolescents need health services in addition to what has been available to them and are more likely to seek services offered at comprehensive sites. Furthermore, with grant support and encouragement, teaching hospitals and community agencies can collaborate to provide comprehensive services to high-risk youth.

Additionally, teaching institutions have increased training available in adolescent health. And in many instances, the training institutions have made substantial efforts to train outside their institutional walls. They have also trained a variety of health care providers.

While comprehensive services to high-risk youth have been made available with grant support, for the most part hospitals and cosponsoring agencies did not merge their separate clinics serving youth into single, comprehensive service sites. Rather, the sponsors and cosponsors have jointly offered services at new sites or at sites belonging to the sponsors or cosponsors. In 18 projects, new, comprehensive clinics have been established at sites where either the sponsor or cosponsor offered other health services previously.

Program experience with consolidation suggests that the financial pressures on health clinics serving youth were not as acute as anticipated in 1981. Indeed, federal and state support for maternal and child health services benefited many sponsors and cosponsors and reduced pressures to consolidate services. During the first two years of the program, no grantee hospital reported the closure of a health clinic serving youth in its community.

Despite the program's requirement that project sponsors and cosponsors develop a strategy for securing support after the grants ended, the sponsoring institutions focused largely on staffing, service start-up, and training during the first two years. Only in the third year did leadership from the sponsoring and cosponsoring institutions begin to consider long-term support and assess the impact of the new financial constraints affecting health care providers. Several grantee institutions, however, have successfully enlisted additional private and public support. During the first two-and-a-half years of the program, 10 sponsor or cosponsor agencies had secured additional grants totaling $2,024,276. Grants ranged in size from a $4,000 city health department grant to support family planning education to a $175,000 grant from a state health department to strengthen a coalition of adolescent service providers.

The goal of long-term support is likely to be even more difficult to achieve than first anticipated due to increased financial pressures on teaching hospitals. The passage of the Omnibus Reconciliation Act of 1981, the Tax Equity and Fiscal Responsibility Act of 1982, and the Social Security amendments of 1983 raised questions in teaching hospitals about the appropriate mix of services they offered

and their continued ability to serve large numbers of uninsured patients (10, 11). The impact of these concerns on community-based efforts such as the high-risk youth program remains to be seen but may be serious.

In many cases, the high-risk youth projects are affected by conflicting pressures from the sponsoring teaching hospitals, the medical schools, and their surrounding communities (12–15). Although some academic medical centers have been under pressure since the 1960s to provide the poor in their communities with more health care (16), the growth in technology and research has contributed to the preoccupation of academic medical centers with tertiary care. The introduction of diagnostic related groups as a basis for inpatient reimbursement by the Medicare program may further increase the focus of many teaching hospitals on their tertiary mission and decrease resources available for primary care.

Given these increasing pressures, is there hope for the survival of philanthropically inspired projects that provide care to the poor or uninsured? It would seem that community-based services sponsored by teaching hospitals may be endangered, and only special efforts are likely to maintain these projects. Two strategies appear useful for preserving the services and training activities for high-risk youth. First, teaching hospitals can approach community organizations such as private foundations or the United Way for support, in essence replacing national philanthropy with local philanthropy. Second, the teaching hospitals and their community cosponsors can seek changes in local or state funding that would increase payments from tax-supported and private insurance programs for services to high-risk young people.

Although private grant programs are a useful way to focus attention on neglected health issues or underserved populations, private grants cannot easily maintain ongoing medical care for a mostly uninsured, poor population, and the greatest challenge for the program described here will be to find long-term support before the grant funds run out.

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laser surgery is an important therapeutic modality and was previously discussed in detail by Dr. V. Cecil Wright and others (references 1 to 10).

It is highly surprising that Drs. Baggish and Dorsey are not aware of the substantial literature on gynecologic laser surgery.

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Reply

To the Editors:

Thank you for the opportunity to reply to Dr. Elias Rubinstein.

This letter represents one of a series written by acquaintances of Dr. V. C. Wright. The list of references is almost identical to that accompanying Dr. Wright's letter. In our opinion this particular correspondence is the most intellectually impaired since Dr. Rubinstein pitifully cites not peer review literature but (1) a personal course workbook compiled by Dr. Wright himself, (2) meetings that Dr. Rubinstein did not attend, (3) a pamphlet of a special interest society, (4) references submitted or published after our article had been received by the AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY. Dr. Rubinstein critically implies that we do not read the literature about laser surgery in gynecology. However, had Dr. Rubinstein's scientific curiosity been minimally piqued he would have needed to read only a few more pages of our description of the combination technique.[1]

This work was first described by one of us (J. H. D.) at an organizational meeting of the Gynecologic Laser Society convened at the Watergate Hotel, Washington, D. C., September 6-8, 1979.

The meeting cited as reference 1 by Rubinstein was a seminar sponsored by another of the authors, (M. S. B.) which of course Dr. Rubinstein did not attend. A substantial body of literature that led to the development of the combination cone was unfortunately neglected by Dr. Rubinstein.[2-9]

We hope that the AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY does not foster this sort of cronyism, since it serves little scientific purpose.

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Maternal death associated with sickle cell trait

To the Editors:

I read with interest your recent article reporting a maternal death in a sickle cell trait patient (Pastorek JG, Seiler B. AM J OBSTET GYNECOL 1985;151:295). I wish to raise a question and make two comments.

First, I would very much like to know the quantity of S hemoglobin your patient possessed. Your article only indicates that she had sickle cell trait (AS). Ordinarily, sickle cell trait patients possess 30% to 40% S hemoglobin; however, rarely there are circumstances in which sickle cell trait patients possess quantities of S

hemoglobin that exceed 50% and they are designated as having SA rather than AS hemoglobin. Was this a possible factor in this patient's death?

I have a comment regarding the autopsy finding of massive sicklemia in all organ systems. Although it was alluded to in your article, I would like to emphasize that such postmortem findings, even with sickle cell trait patients, is the rule rather than the exception. However, almost always they represent changes that occurred after death when, of course, there is total deoxygenation of both arterial and venous blood. Hence, one actually cannot assume that these postmortem sickle cell changes also preceded the agonal event.

Lastly, it is interesting to note that your patient had premature rupture of the membranes. I am familiar with a single uncontrolled retrospective study in the literature which suggests that premature rupture of the membranes occurs more frequently in sickle cell trait patients than in the general population. Perhaps this finding for sickle cell trait patients warrants further study.

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Reply

To the Editors:

We appreciate Dr. Foster's comments regarding autopsy findings of massive sicklemia in patients with sickle cell trait. As we mentioned in the paper, this is far from conclusive evidence that a sicklemia is a direct cause of problems in these patients. We are making a clinical observation with the intention of arousing interest in this matter. Perhaps further case studies, including antemortem red cell morphologic studies will clarify this matter.

We thank Dr. Foster for his clinical observation that premature rupture of the membranes may be associated anecdotally with sickle cell trait. We are currently engaged in a large multicenter cooperative study funded by the National Institutes of Health which examines prematurity, premature rupture of the membranes, etc., from the point of view of genital infectious etiology. However, once this study of 15,000 to 20,000 patients is completed, there should certainly be enough data to include sickle cell trait as a variable in patients with premature rupture of the membranes.

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Confirmation of xeroradiography as an important postmortem fetal diagnostic technique

To the Editors:

We were delighted to see the recent report by Elejalde and associates stressing the importance of xeroradiographic imaging techniques for fetal material (Elejalde BR, Elejalde MM, Gilman M. AM J OBSTET GYNECOL 1985;151:666). Our program has been using this technique for the past 6 years, and we have also found it to be a useful approach for examining aborted fetuses. In our study we emphasized the enhanced visualization of soft tissues with this technique and reported examples of such fetal abnormalities as acardia, neural tube defects, nuchal cystic hygroma, and arthrogryposis. Using newborn kittens and chickens, we were able to compare images derived from standard radiographs, xeroradiographs, and alizarin staining. The quality of the xeroradiographic images is clearly superior. We were delighted to see this technique applied to skeletal dysplasias and also to witness the use of contrast media to better visualize hollow viscera.

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SPECIAL ARTICLES

The High-Risk Young People's Program

A Summing Up

JULIA G. LEAR, Ph.D., HENRY W. FOSTER, JR., M.D., AND JENNIFER A. BARATZ, B.A.

For over five years, 21 teaching hospitals and 54 community cosponsors provided health services to young people at risk for sociomedical problems, i.e., to young people living in communities characterized by high rates of teen pregnancy, sexually transmitted disease, drug abuse, alcohol abuse, accidents, homicide, suicide, and mental illness. With support from The Robert Wood Johnson Foundation, the 20 grantees of the High-Risk Young People's Program developed projects whose collective goal was to expand services to high-risk youth and improve their health. This goal was to be achieved by a direct provision of medical services, training health providers in the care of high-risk youth, consolidating categorical youth services into single, comprehensive care sites, and securing long-term support for these new services and training activities. During the grant period, 114 fellows, 974 residents, 453 medical students, and 126 graduate nurses trained at project sites. Patient visits, which totaled 47,203 the first year, reached 84,754 the second year, and were reported at 89,024 in the fourth year. Sixteen of the 20 projects secured 117 grants worth nearly $7 million. We conclude that the projects were successful in training health care providers and in securing additional support for Program purposes, but were less successful in expanding services beyond the initial pilot for clinical care.

KEY WORDS:
At-risk youth
Comprehensive services
Adolescent medicine fellow
Pediatric training

From 1982 through 1986, 21 teaching hospitals working with 54 community cosponsors initiated projects to provide community-based health services to young people at-risk for serious socioeconomic and medical problems, including adolescent pregnancy, drug abuse, alcohol abuse, sexually transmitted disease, accidents, homicide, suicide, and mental illness. With support from The Robert Wood Johnson Foundation, the institutions listed in Table 1 received grants through the Program to Consolidate Health Services for High-Risk Young People to initiate services to improve the health of young people. To achieve this goal, the projects each pursued four objectives: 1) increase health services to high-risk youth, 2) train health professionals in the care of high-risk youth, 3) consolidate health services into comprehensive care centers, and 4) secure long-term support for adolescent health services.

The basic approach to achieving these objectives was through the development of consolidated health services sponsored by teaching hospitals and community-based health agencies. Clinical faculty, residents, and fellows from a teaching hospital could join with selected agency staff to provide care in each of several locations frequented by young people (1). Offering a broad range of services helped make care more accessible to individuals with multiple health problems.

In addition to the project grants, The Robert Wood Johnson Foundation awarded grants to Meharry Medical College and Georgetown University

From Children's Hospital National Medical Center, Washington, D.C. (J.G.L., J.A.B.) and Meharry Medical College, Nashville, Tennessee (H.W.F.)

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Table 1. Project Cities and Institutions

Baltimore
- *Baltimore Youth Health Project*
- University of Maryland*
- Baltimore City Health Department
- *Hopkins Adolescent Program*
- The Johns Hopkins Hospital*
- Baltimore City Health Department

Boston
- *Boston Youth Program*
- Boston City Hospital*
- Dorchester House Multi-Service Center
- Harvard Street Neighborhood Health Ctr
- Roxbury District Court
- Boston Public Schools V & VI

Chicago
- *Project for Austin Teen Health* (PATH)
- Cook County Hospital*
- Chicago Comprehensive Care Center
- Austin High School
- Chicago Department of Health

Cincinnati
- *Coordinated Adolescent Services Team*
- University of Cincinnati Hospital*
- Central Psychiatric Clinic
- Cincinnati Department of Health

Cleveland
- *Cleveland Adolescent Health Care Project*
- Cuyahoga County General Hospital*
- Free Medical Clinic of Greater Cleveland
- Hough-Norwood Family Health Care Center
- Thomas F. McCafferty Health Center

Dallas
- *Dallas High-Risk Youth Project*
- Parkland Memorial Hospital*
- Dallas Countrywide Health Department
- University of Texas Health Science Center at Dallas

Detroit
- *Young Detroit Health Center*
- Children's Hospital of Michigan*
- Detroit Department of Health
- Henry Ford Hospital
- Hutzel Hospital
- United Community Services of Metropolitan Detroit

Hartford
- *Young Adults Program*
- University of Connecticut Health Center*
- Hartford Health Department
- Connecticut Department of Health Services
- Project FIRE, Addiction Services Division Connecticut Department of Corrections
- St. Francis Hospital & Medical Center

Indianapolis
- *Indiana University Hospitals**
- Marion County Health Department

Jackson, Mississippi
- *University of Mississippi/Jackson-Hinds Project*
- University of Mississipi Medical Center*
- Jackson-Hinds Comprehensive Health Center
- Jim Hill High School
- Murrah High School

Los Angeles
- *L.A. High-Risk Youth Project*
- Children's Hospital of Los Angeles*
- Los Angeles Free Clinic

New Haven
- *Adolescent Services Project*
- Yale-New Haven Hospital*
- Fair Haven Community Health Clinic

New York
- *The HUB*
- Bronx-Lebanon Hospital Center*
- Planned Parenthood of New York City, Inc.
- *Bronx Consortium for Adolescent Health*
- Montefiore Hospital & Medical Center*
- Bronx Municipal Hospital Center
- North Central Bronx Hospital
- Dr. Martin Luther King, Jr. Health Center
- The Comprehensive Family Care Center
- Montefiore-Morrisania Comprehensive Care Center

Oklahoma City
- *Oklahoma Adolescent Health Project*
- Oklahoma Children's Memorial Hospital*
- Oklahoma Department of Mental Health
- Oklahoma Area Indian Health Service
- Cherokee Nation of Oklahoma
- Oklahoma State Health Department
- University of Oklahoma Health Sciences Center

Rochester, New York
- *Community Adolescent Services*
- Strong Memorial Hospital*
- Anthony Jordan Health Center
- Monroe County Health Department
- Threshold Center for Alternative Youth Services, Inc.

San Diego
- *San Diego Teen Connection*
- University of California, San Diego School of Medicine*
- Imperial Beach Community Clinic
- Operation Samahan Health Clinic
- Otay Community Clinic
- San Ysidro Community Health Care Center

San Francisco
- *San Francisco High-Risk Youth Project*
- University of California, San Francisco*
- San Francisco General Hospital*
- Hospitality House of San Francisco
- Mount Zion Hospital & Medical Center of San Francisco
- San Francisco Children's Hospital
- San Francisco Kaiser Permanente Medical Ctr
- San Francisco Public Health Department

Washington, D.C.
- *Project to Consolidate Health Services for High-Risk Youth*
- Howard University Hospital*
- Center for Youth Services
- D.C. Department of Human Services

*Grantee institution

to support Program offices to monitor project performance and provide technical assistance to grantees.

The Johnson Foundation also awarded a grant to Washington University in St. Louis to conduct a program evaluation. The evaluation, to be completed in 1988, addresses four questions: Does the comprehensive health care system supported by the Program discover the problems of adolescent patients? Do Program-sponsored clinics make services available to address those problems? Is a plan of care developed and implemented? and Is the health of the young people served by the Program clinics improved?

Program History

In July 1981, a brochure inviting application to the High-Risk Young People's Program was mailed to teaching hospitals, public health departments, and others concerned with high-risk youth. One hundred forty-two letters of intent were received and 90 completed applications were submitted. In January 1982, 20 grants were awarded by the Foundation. Each grantee received $600,000 over a 4-year period.

The 20 funded projects agreed to (1) make health care for high-risk young people in their community more accessible, (2) develop consolidated, comprehensive services that meet the serious problems of high-risk adolescents, (3) train health professionals in the care of high-risk youth, and (4) secure long-term support for project-initiated activities.

The 21 sponsoring teaching hospitals were linked to 54 community cosponsors, including 14 neighborhood health centers, ten city health departments, nine nonprofit community agencies, seven additional hospitals, five public schools, and nine diverse other organizations (e.g., a multiservice center for youth, the Cherokee Nation, and a family planning clinic).

Increasing Access to Health Care

Project-supported patient care was established in 56 clinic sites. Some projects opened special adolescent medical services within already established city or county health department clinics (17), neighborhood health centers (12), or hospital outpatient departments (10). Others initiated clinics in new sites such as high schools (8), multiservice centers for youth (4), three private medical clinics, and two juvenile detention centers.

Table 2. Patient visits by Grant Year

Project center	Grant year 1	2	3	4	Total
Boston City	561	1315	2924	2225	7025
Bronx-Lebanon	4744[a]	11529[a]	11610[a]	13221[a]	41104[a]
Children's, LA	1905	2631	3001	2410	9947
Children's, Michigan	244	2086	2270	2399	6999
Cuyahoga County	2465	3340	5358	6870	18033
Cook County	1879	3157	2980	5081	13097
Howard University	633	1248	2206	1936[b]	6023
Indiana University	4002	15947[a]	6455	5982	32386
Johns Hopkins	502	1555	1302	1531	4890
Montefiore Medical Center	11509[a]	11803[a]	12571[a]	9891[a]	45774[a]
Oklahoma Children's	N.A.	439	885	1315	2639
Parkland Memorial	1246	3557	2986	3924	11713
Strong Memorial	7723[a]	7677[a]	8961[a]	5794[a]	30155[a]
UCSD Medical Center	472	954	1198	988	3612
UCSF/San Francisco General	2044	4443	5795	5710	17992
University of Cincinnati	261	NA	707[a]	4030[a]	4998[a]
University of Connecticut	830	1677	1953	2041	6501
University of Maryland	2450	4001	367	4177	14235
University of Mississippi Medical Center	524	1695	2356	2901	7476
Yale/New Haven	3209	5700	6324	6598	21831
Total	47203	84754	85449	89024	306430

[a]This number includes a substantial number of nonproject patients.
[b]Projected figure based on first-quarter data.
[c]Data from one quarter submitted.

The clinics were staffed by a variety of health professionals including medical faculty, fellows, residents, nurse practitioners, nurse midwives, social workers, health educators, and other allied health workers. There was no standard staffing pattern.

Table 2 summarizes visits by high-risk youth to Program-supported clinics and documents project success in organizing clinic services. Given the multiple goals for each project, 2000 patient visits per year as a minimum objective for patient care activities was established. By the end of 4 grant years, 16 of the 20 projects (80%) were seeing patients at at least that rate.

The type of patient seen in the clinics changed little during the 4 years. The patients were predominantly ages 15–19 years (62%) and female (73%). Three fourths of the clinics reported patients' race and slightly more than half were black, 30% white, and 16% Hispanic. The continued underrepresentation of young men using these services was disappointing, particularly as many projects had made a considerable effort to attract this population.

Improving community-based services was also an important Program objective. Table 3 shows that 18

Table 3. Weekly Clinic Hours During Grant Year 4

Project Centers	Total clinic hours	Community-based clinic hours	Percent community
Boston City	56	21	38
Bronx-Lebanon	41.5	41.5	100
Children's, LA	8	8	100
Children's, Michigan	15.5	15.5	100
Cuyahoga County	43.5	19.5	45
Cook County	42	30	71
Howard University	12	12	100
Indiana University	55.3	55.3	100
Johns Hopkins	23	5	22
Montefiore Medical Center	41	34	83
Oklahoma Children's	31	31	100
Parkland Memorial	40	0	0
Strong Memorial	40	40	100
UCSD Medical Center	15	13	100
UCSF/San Francisco General	85	85	100
University, Cincinnati	21	21	100
University of Connecticut	32	0	0
University of Maryland	20	20	100
University of Mississippi Medical Center	97.5	80	82
Yale/New Haven	13	13	100
Total hours	730.25	544.75	75

of the 20 projects offered clinic hours in the community. Of these, 12 (67%) held all of their clinic hours at these sites. Six projects sponsored clinic hours at three or more community sites.

One contribution of the Program was to facilitate teaching hospital activities in the community. Although the extent of off-campus service and education was not documented, in 1980 the Association of Academic Health Centers (AAHC) estimated that between 5 and 10% of medical education occurred in the community and reported that "this extent is considerably greater than it was 15–20 years ago" (2).

Although the projects were successful in their initial goal of establishing comprehensive health services for adolescents, it is less clear whether the health services were delivered to medically homeless high-risk youth. None of the projects reported information on patients' previous sources of care. Thus, it is not known to what extent these clinics saw a mostly unserved population; replaced episodic, fragmented care with continuous, comprehensive care; or became one of several provider clinics visited by the patients.

As is evident from Table 2, patient volume at most clinics grew quickly during the first year of operation and plateaued after 2 years. The Program-supported clinics were by and large not expanded or replicated during the life of the grant and, therefore, the clinics have remained local models and have not initiated new systems of care for adolescents in the community.

Training Health Professionals in the Care of High-Risk Youth

Although the primary objective of the Program was to increase access to care for high-risk youth by direct provision of services in the community, the Program also sought to increase access to medical services by training a variety of health professionals in the care of high-risk youths (Table 4).

Fellowships

Grant funds could be used to support a postdoctoral fellow interested in the health problems of high-risk young people. Seventeen of the 20 projects trained at least one fellow during the grant. One hundred fourteen fellows completed training in project-affiliated clinical sites, of which 69 were supported with Johnson Foundation funds.

Although the Program did not specify the fellowship discipline it would support, in practice, fellowship support became synonymous with support for adolescent medicine fellowships. A behavioral medicine fellowship at the University of Maryland, a child/adolescent psychiatry fellowship at University Hospital in Cincinnati, and minifellowships in adolescent health for community physicians at Children's Hospital of Michigan were among those funded. The adolescent medicine fellowships (16) were primarily 1-year clinical fellowships, with five pediatric departments offering 2-year programs.

Although the Program trained significant numbers of postdoctoral fellows, it was less successful in securing long-term support for these Program-generated fellowships. Only seven of the 17 teaching hospitals intend to continue their fellowships in the postgrant period. The reasons given were funds were not available and/or the adolescent medicine fellowship did not have the support of the pediatrics department.

Resident Training

In addition to grant-supported fellowships, the teaching hospitals provided substantial training for

Table 4. Program-Sponsored Training in Adolescent Health Care

Project centers	ADOLESCENT MEDICINE FELLOW	Program supported	Program affiliated	RESIDENTS	Pediatrics	Family medicine
Boston City	1	1	—	25	15	—
Bronx-Lebanon	—	—	—	66	54	—
Children's, LA	17	4	13	111	73	21
Children's, MI	5[a]	5	—	132	75	—
Cook County	12.5[b]	3.5	9	35	33	2
Cuyahoga County	4	2	2	54	26	26
Howard University	3	3	—	39	36	—
Indianapolis University	2	2	—	48	48	—
Johns Hopkins	2	2	—	88	88	—
Montefiore Medical Center	6	6	—	177	160	—
Oklahoma Children's	—	—	—	—	—	—
Parkland Memorial	4	4	—	22	16	6
Strong Memorial	6	3	3	32	17	11
UCSD	7	7	—	47	38	9
UCSF	24	14	10	44	32	8
University of Cincinnati[c]	1	—	1	1	—	—
University of Connecticut	—	—	—	29	29	—
University of Maryland	14[c]	6	8	—	—	—
University of Mississippi Medical Center	2	2	—	24	24	—
Yale/New Haven	4	4	—	—	—	—
Total	114.5	68.5	46	974	764	83

[a]The adolescent medicine fellowship at Children's Hospital of Michigan trains community physicians in a 3-month minifellowship.
[b]The 0.5 indicates a fellow who left Cook County Hospital midway through training.
[c]The University of Maryland has had two Adolescent Medicine fellows and four Behavioral Pediatrics fellows supported by the grant, and eight Behavioral Pediatrics fellows affiliated with the project.
[d]This fellowship was a child/adolescent psychiatry fellowship.

974 house officers in Program-related clinics. The residency training programs varied widely. Some were required rotations, while others were elective. Some involved year-long continuity clinics, while others offered 1-month rotations to introduce the issues involved in treating high-risk adolescents.

Of the 17 projects offering resident training, 14 offered training at out-of-hospital sites. The majority (78%) of the residents were from pediatrics, with the remaining from family practice (9%), internal medicine (6%), obstetrics–gynecology (5%), and psychiatry (2%).

Due at least in part to the recent increase in emphasis on ambulatory and community-based training for primary care house officers, 15 of the 17 projects offering residency training in adolescent health care will continue to do so at the conclusion of grant support.

Other Graduate Training

A slightly different set of 17 projects sponsored clinical education for other graduate level trainees including medicine, nursing, psychology, and social work. The future of these clerkships is less clear, but it appears that most projects anticipate continuing them.

Clinic Staff

A significant contribution of the Program's training effort has been the development of structured in-service training for clinic staff members. Typically, this training involved monthly didactic presentations as well as an increased frequency of case conferences. All 20 projects offered clinic staff training. Project cosponsors, which generally provided clinic space as well as support staff for the clinics, considered staff training one of the most important benefits of Program participation. Ten of the clinic staff training programs are scheduled to continue in the post-grant period.

Community Providers

Health professional training also included education for community providers. Fourteen of the 20 projects developed lecture series, citywide conferences, and

Table 4 (*continued*)

Psychiatry	Internal medicine	Ob/Gyn	OTHER GRADUATE TRAINEES	Medicine	Nursing	Psychology	Social work	Other	UNDER-GRAD TRAINEES	CLINIC STAFF	COMMUNITY PROVIDERS
—	10	—	7	—	—	7	—	—	—	80	600
6	—	6	6	1	—	—	5	—	—	21	—
2	12	3	36	36	—	—	—	—	2	120	4,191
—	26	31	7	—	6	—	1	—	3	49	199
—	—	—	15	3	—	12	—	—	—	14	—
—	2	—	143	136	—	—	3	4	—	40	140
2	—	1	63	39	2	—	—	22	—	23	250
—	—	—	13	11	—	—	—	2	—	200	200
—	—	—	—	—	—	—	—	—	—	8	—
11	6	—	39	36	—	—	3	—	—	15	—
—	—	—	101	—	70	14	15	2	—	13	585
—	—	—	22	12	6	4	—	—	—	24	200
—	—	4	42	8	14	4	4	12	11	60	92
—	—	—	115	115	—	—	—	—	—	60	—
—	4	—	70	28	16	8	8	10	40	20	24
1	—	—	3	—	—	1	2	—	—	21	107
—	—	—	55	26	3	—	3	23	—	16	465
—	—	—	—	—	—	—	—	—	—	28	—
—	—	—	—	—	—	—	—	—	—	12	75
—	—	—	16	2	9	—	1	4	6	15	288
22	60	45	753	453	126	50	45	79	62	839	7,416

workshops targeted for health professionals in the community. Most projects found great interest in the problems of high-risk youth and that little recruitment to training sessions was necessary. Several projects increased physician participation by offering continuing medical education credit. The projects did not consistently report the number of community presentations made by the staff; the 7,416 community providers participating in project education is probably an understatement of provider education.

Consolidating Health Services for High-Risk Young People

The Program's consolidation activities, more accurately described as cooperation and networking, did not reflect the original Program intent. Originally, Program planners believed that youth-serving categorical clinics such as drug treatment and family planning would be threatened when federal dollars for health and welfare shrank in the 1980s. Foundation dollars were intended to encourage the integration of categorical services into more efficient, less expensive, single-stop, comprehensive clinics. Thus, services could be maintained even if the number of service sites diminished. Such consolidation did not occur.

Program participants approached consolidation by the sponsor and cosponsor organizations offering comprehensive services (1) in a site where the sponsor or cosponsor had previously provided other health services (19 projects) and/or (2) in a new site (seven projects).

Some projects also pursued consolidation through joint planning and participation in other collaborative efforts. Twelve projects participate in community-wide adolescent health and/or teenage pregnancy networks. The sponsor and cosponsor organizations of 11 projects have initiated new joint grant applications.

Securing Long-Term Financial Support for Project Activities

The Program mandated that all projects seek post-grant funding to continue services and training. Although most projects focused on clinic staffing, service start-up, and training for the first two Program years, in the latter two years, fund raising became a priority. Seventeen of 20 projects secured long-term support for grant-initiated clinical services, and 15 of the 20 planned to maintain a portion of their training efforts.

From 1983 through 1986, 16 of the 20 projects received nearly $7 million from 117 grants. In 1983,

$763,000 was raised through 19 grants; nearly $2.0 million was raised in 1984 (34 grants), $2.4 million in 1985 (31 grants), and $1.8 million in 1986 (33 grants). The average awards size in each year, respectively, was $40,158, $58,701, $78,075, and $54,873.

City and county support was the smallest source of revenue ($1.1 million). The federal government, state government, and private philanthropy provided similar levels of support at $1.7 million, $1.97 million, and $1.99 million, respectively. The average size of grant awards varied widely: 21 local government grants averaged $54,770; 18 federal grants $94,650; 32 state grants $61,663, and 47 private foundation grants $42,314.

Other Issues in Program Development

Two issues of Program development related specifically to the teaching hospital sponsorship of the projects: (1) interdepartmental cooperation in services and training in adolescent health care, and (2) linking patient care provided by the community-based clinics, the hospital outpatient/emergency room services, and the inpatient adolescent medicine service.

Pediatric departments initiated projects in 17 of the 20 sites. Site visit teams repeatedly urged the inclusion of representatives from psychiatry, psychology, family practice, and obstetrics/gynecology in project efforts. Some pediatric departments appeared to use the grant activities to link their services more closely to other hospital departments.

Providing a comprehensive system of care for adolescents through the High-Risk Program was more difficult in at least five institutions because the projects being developed by the pediatric departments did not control the hospital's outpatient pediatrics services. Thus, linking the community-based clinics to the hospital outpatient department (OPD) and the inpatient services was difficult because referrals, OPD registration, and patient follow-up could not be served by the same staff.

Future Plans for Program-Initiated Activities

At the completion of the 4 years of the Program, most of the 20 projects reported they would maintain the service and training activities initiated with grant support. Seventeen of the 20 will continue to staff clinics targeted for high-risk youth, and 15 will maintain at least a portion of their training activities. Funding will come primarily from new or redirected monies available from cosponsoring institutions (particularly city health departments) or from grant support provided by public and private agencies.

The continuing support for the Program projects can be attributed primarily to two factors: the projects for the most part did what they set out to do over 4 years and they made a mark in their communities; and in many communities, regions, and states, there is a growing awareness of adolescent problems and support for targeted services. Project directors comment that at the beginning of the Program they thought the problems of high-risk youth were understood. Only after initiating the project did they realize that public education about high-risk issues in their communities would have to be a priority.

Both to encourage public awareness and to respond to public concerns, staff members in many projects worked with local, state, and national organizations on high-risk youth issues. Many served on a gubernatorial task force, testified before the state legislature, reviewed guidelines for state initiatives, chaired citywide coalitions on adolescent pregnancy, advised federal government agencies, made presentations to foundations, and contributed to their professional organizations. The end result has been not only on-going support for many of their own efforts, but also expanded resources to address the needs of adolescents throughout the country.

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Presentation

A MODEL FOR INCREASING ACCESS: TEENAGE PREGNANCY PREVENTION

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INAPPROPRIATE TEEN PREGNANCY has become a major social issue in this country. The point of emergence of this problem is not clear. However, the single publication that seemed to galvanize awareness of this national dilemma appeared in 1976.[1] This article, "Eleven Million Teenagers: What Can Be Done About the Epidemic of Adolescent Pregnancies in the United States," jolted the nation into realizing the magnitude of the problem.

Although birth rates for females less than 20 years of age declined during the 1970s, adolescent pregnancy remains an overwhelming problem.[2,3] More than one million teenage pregnancies, most of them unplanned, will occur in our country this year, with nearly 500,000 births. The United States ingloriously leads all other western nations in this category by nearly a two-fold margin.[3] This is a problem that affects all ethnic, social, and economic classes. Discounting the non-white contribution to our nation's teenage pregnancy and birth rates does not change our statistical ranking relative to other western nations.

It has been incorrectly presumed that other western nations have lower birth rates than the United States because of their higher abortion rates. In fact, abortion rates in the United States are substantially higher than those for other western countries.[4] Additionally, in Sweden and France, teenagers become sexually active at an earlier age than do teenagers in our country, yet their pregnancy rates remain substantially lower than ours.

The adverse human and economic consequences of teen pregnancies are enormous. Higher school drop-out rates, subsequent unplanned pregnancies, and reduced marketable skills are all likely consequences for teenagers who become pregnant. According to one study, the estimated single-year direct cost to the public of teenage pregnancy in 1985 was $16.65 billion.[5] This study also found that if all teenage births were delayed until age 20 or later, the potential

savings to the public would be $2.06 billion for the entire cohort of teenagers who would otherwise have had a first birth in 1985. The human and economic consequences of unintended childbearing are evident.

This is particularly true for certain teenagers. Poor perinatal outcome is more closely associated with low socioeconomic status (SES), poor antenatal nutrition, poor general health, and drug use than with maternal age.[47] In a recent review, researchers concluded that there is a relationship between poverty and poor reproductive status.[5] Moreover, it has been acknowledged that adolescent parents tend to come from high-risk families.[5]

Clearly, our incidence of teen childbearing is unacceptably high. Innovative approaches must be created and applied to seek some redress from this problem.

Rationale for program design

It is apparent from the continuing high rates of teen pregnancy in this country that previous efforts to attack this problem are wanting. In a preliminary report to the Rockefeller Foundation, Dryfoos observed that strategies for pregnancy prevention programs, particularly for adolescents, historically tend to follow one of three general approaches: to (1) impart knowledge, (2) provide access to contraception, or (3) enhance life options.[3] Clearly, there is some overlap, but most programs stress one of these approaches.

Despite agreement that American youth need knowledge about human reproduction in order to act responsibly in matters of sexuality, there are, nonetheless, continuing barriers to the availability of this education, and indeed conflicting studies as to its value.[3,42] However, the literature does show that sex education programs are most likely to be effective when actively coupled with direct access to contraceptives. Reciprocally, it stands to reason that the effectiveness of predominantly service programs will be decreased if not coupled with sex education.

The "newcomers" on the block are programs that focus on the enhancement of life options by strengthening adolescents' self-esteem. An award-winning series by *Washington Post* reporter Leon Dash clearly shows that the capacity to prevent pregnancy without the desire to prevent it is ineffective in lowering teen pregnancy rates.[34] Adolescence is a time when one's self-esteem is developing, and hence fragile. The academic community formally realized the immense special needs of adolescents only about 30 years ago. The Society for Adolescent Medicine was founded in 1968; the American Medical Association recognized adolescent medicine as a structured specialty in 1977; and the American Academy of Pediatrics formed a section on adolescent health in 1978.

Despite this formal recognition of adolescents' special needs, the Robert Wood Johnson Foundation realized in 1981 that the health care needs of so many adolescents were going unmet. The Foundation provided funds to 20 teaching hospitals to support community-based comprehensive health services to young people living in communities with high rates of sociomedical problems, such as

adolescent pregnancy, drug and alcohol abuse, depression, and traumatic death from accidents, homicides, and suicide.[8] The training of health professionals in the care of high-risk young people was also a major objective of this funding effort. Hence, during the four years of program activities, in addition to providing health-related visits to approximately 306,000 young people, the foundation provided formal training in the care of adolescents to 115 adolescent medicine fellows; 974 medical residents; 753 graduate trainees in medicine, nursing, psychology, social work, and other fields; and 62 undergraduate trainees.

Although the service sites for most of the projects were neighborhood health centers, public health departments, and hospital outpatient centers, five of the sites were public schools. As a consequence, the Robert Wood Johnson Foundation has subsequently funded a new national effort entitled, "School-Based Adolescent Health Care Program." These programs address to varying degrees the issue of teen sexuality and pregnancy prevention. The ability of school-based programs to successfully provide pregnancy prevention services is well known.[9,10] However, despite their many advantages, significant gaps remain in the capacity of school-based programs to deliver services.

Community-based intervention

These service limitations of school-based health clinics led to the emergence of a residential venue. The selection of a community-based intervention is a major unique aspect of the I Have A Future (IHAF) Program at Meharry Medical College. Unlike many programs built around the concept of enhancing life options, the Meharry program is not anchored in schools, but in a residential setting—the public housing projects.

A residential venue has several major advantages. First, this setting allows us to more adequately address idle time (evenings, weekends, and summers) than do school-based programs. Second, community-based centers such as these are open to all adolescents, including students who have dropped out or have been expelled from school. Third, the closer proximity to families provides a better opportunity to involve parents and siblings. Finally, the residential setting enables the program to operate within the full range of situations that characterize life in the public housing projects.

This effort to more fully involve families and the social matrix of the immediate community is thoroughly consistent with a report on teen pregnancy from a panel of the U.S. Secretary of Health and Human Services.[11] The tone of that 1989 report was set in its executive report: "Reshaping community climates, the Panel agreed, had to be the goal of prevention efforts. The Panel wanted to help communities to develop and strengthen environments in which adolescent pregnancy was not the norm, environments in which youth would recognize positive life options, and achieve their greatest potential."

The position set forth by this panel is the very embodiment of the IHAF Program, which was designed and put into operation in 1986.

Staff and administrators were keenly aware from the very onset that community support and trust were essential for the success of this intervention. Hence, we made initial contact with the Council of Presidents of the Metropolitan Davidson County Housing Authority (MDHA) Residents' Association, which represents all residents of Nashville's housing projects. With this organization, its president, and officials from the MDHA, two study sites and two control sites were mutually agreed upon.

In the process, MDHA officials, the Council of Presidents, and community representatives worked with Meharry Medical College principals, and mutually agreed to the conceptual framework of the IHAF program. The need to enhance life options for the youth of these communities was emphatically accepted by all. The group also recognized that attacking the problem of teen pregnancy must involve more than providing access to information and contraception, and that a narrow focus that isolates teenage sexuality from the broader psychosocial context would be inappropriate and ineffective. The IHAF Program is built on the promise that changes in sexual behavior should be pursued within a framework that enhances self-image and presents positive alternative futures.

To develop a replicable community-based life enhancement program that reduces the incidence of early pregnancy and childbearing among high-risk youth, the I Have A Future Program has incorporated the following objectives: (1) to improve knowledge and attitudes related to personal health, including awareness of human sexuality, the effects of drug and alcohol abuse, and other behaviors that may place youth at risk; (2) to provide ready access to and to increase utilization of comprehensive adolescent health services; (3) to increase socially adaptive and appropriate behavior with particular focus on school achievement, vocational development, and delinquency rates, and to enhance the ability of high-risk adolescents to overcome environmental barriers in attaining the skills necessary to pursue meaningful employment and educational opportunities with a promise of upward mobility; (4) to engender a more positive self-concept and constructive attitude toward community, family life, and the future; and (5) to expand educational opportunities for health professional students through a community-based program serving high-risk adolescents.

We felt that the concepts contained in this proposal were unique and warranted implementation, if for no other reason than they had not been previously attempted. Hence, we submitted a grant proposal to the Carnegie Corporation, which subsequently conducted a site visit. In the fall of 1986, the Carnegie Corporation awarded a grant to implement the first half (3.5 years) of the intervention. The following year, the W.T. Grant Foundation funded the program's research efforts. We hired staff, secured office space, and completed other preliminaries in late 1986 and early 1987, and held formal opening ceremonies on February 11, 1987. Approximately 200 people attended, representing a wide cross-section of individuals and organizations, including the Office of the Mayor.

Programmatic activities

The I Have A Future Program provides both individual and group activities to give access to comprehensive health services; to increase social adaptability; to provide pre-vocational skills, social activities, and ongoing counseling as needed; and to enhance parent/family development.

The youth range in age from 10 to 17, and the program is designed to be sensitive to all developmental needs and abilities. Consequently, the curriculum emphasizes knowledge, attitude, and awareness for early adolescents, and behaviors for older adolescents. The following values permeate all aspects of the program: self-esteem; physical and mental well-being; completion of school; the development of job skills; sexual responsibility; self control and ability to handle interpersonal conflict; the value of helping others; pro-social attitudes; and family values with appropriate parenting.

Examples of ongoing and planned activities include modules that meet all of the objectives. In each module are exercises and presentations to teach an edited version of Nguzo Saba, Seven Principles of Blackness—Pro-Social Attitudes, which were created by Dr. Maulanga Karenga. The following Nguzo Saba principles, drawn from Swahili, are reviewed on a daily basis:

(1) Umoja (Unity)—to strive for and maintain unity in the family, community, nation, and race;

(2) Kujichagulia (Self-determination)—to defend ourselves, name ourselves, and speak for ourselves instead of being defined and spoken for by others;

(3) Ujima (Collective work and responsibility)—to build and maintain our community together, and to make our brothers' and sisters' problems our problems and to solve them together;

(4) Ujamaa (Co-operative economics)—to build and maintain our own stores, shops, and other businesses and to profit together from them;

(5) Nia (Purpose)—to make as our collective vocation the building and developing of our communities in order to restore our people to their traditional greatness;

(6) Kuumba (Creativity)—to do always as much as we can, in the way we can, in order to make our community more beautiful and beneficial than when we inherited it;

(7) Imani (Faith)—to believe with all our hearts in our parents, our teachers, our legitimate leaders, our people, and the righteousness and victory of our struggle.

Numerous modules have been offered and are being planned to address each of the objectives of the I Have a Future Program. Table 1 illustrates the relationships between the modules and the objectives. The projects and modules are described below.

Tutorial/Academic Enrichment Module: This component of the program arose from the responses of parents to an IHAF Community Needs

TABLE 1
RELATIONSHIP BETWEEN MODULES AND OBJECTIVES

Objective 1: To improve knowledge and attitudes related to personal health.	• Alcohol and Drug Education • Family Life Education • BARN, the Body Awareness Resource Network computer program • CHARM • MATURE • Athletics, Recreation, and Summer Olympics • Comprehensive Health Services
Objective 2: To provide ready access to and increase social services including contraceptive availability.	• Comprehensive Health Services
Objective 3: To increase socially adaptive/ appropriate behaviors with focus on school achievement, vocational skills development, etc.	• Tutoring • Job Readiness Training • Entrepreneurial Program • BARN, the Body Awareness Resource Network computer program • CHARM • MATURE • Neighborhood Watch • Athletics, Recreation, and Summer Olympics
Objective 4: To engender a more positive self-concept and constructive attitude toward community, family life, and the future.	• BARN, the Body Awareness Resource Network computer program • CHARM • MATURE • Job Readiness Training • Tutoring • Entrepreneurial Program • Athletics, Recreation, and Summer Olympics
Objective 5: To stimulate improvement in psychosocial development	• All modules

Survey. The six-week enrichment module is an ongoing program designed to improve participants' test scores on the Tennessee State School Proficiency Exam and to help the youth improve their grades. Youth are taught test-taking strategies and homework study skills. The program is designed to teach youth how to be peer counselors.

CHARM (Choosing How to Adorn and Refine Myself) and MATURE.

(Males Adorning, Thinking, and Using Refined Energies): CHARM and MATURE are eight-week programs designed for females and males, respectively. They are used to improve personal appearance. Activities center around knowledge, attitudes, and behaviors in relation to personal hygiene and health. The programs incorporate several methods of presenting material. Youth are exposed to guest speakers, field trips, psychodrama, and group discussions, as well as information about famous female and male writers, poets, and other role models.

Family Life Education Module: The Family Life Education Module is a fifteen-week program in which youth are provided with information regarding family roles and responsibilities through all stages of life. The objectives are to help them understand the meaning of family; to identify and discuss various roles of family members; to discuss family growth and development; and to improve knowledge of sexuality and contraceptives. Particular emphasis is placed on improving decision-making skills and setting goals in the family context. Interpersonal relationships, intimacy, and communication are discussed in great detail. The overall objective is to generate positive attitudes and values towards contraception and abstinence.

Job Readiness Module: The Job Readiness/Job Skills Program is an eight-week module designed to address career development, job attainment skills, and job survival. Each participant performs various activities and exercises and are then helped to find summer employment.

IHAF Youth Entrepreneurial Program: To promote vocational and career development, the Entrepreneur module provides opportunities to help youth plan for the future. IHAF uses new ways of expanding youths' opportunities by helping them develop more adequate life skills, positive life options, and personal hopes for a more fulfilling future. The Youth Entrepreneurial Program is designed to help teenagers learn more about themselves and about the world of work by starting a business within their community. Youth have the opportunity to participate in a Job Readiness and Career Development class while being gainfully employed for 10 hours a week marketing and distributing pro-social attitude materials. Sixty to 100 youth later enter the Entrepreneurship segment, in which they are encouraged to create, plan, and implement their own businesses. This particular project is viewed as a potent vehicle to motivate and train youth for future careers. It is a way to empower them, using skills and abilities and their own creativity.

Alcohol and Drug Abuse Prevention Module: In accordance with the respondents of the IHAF Community Needs Assessment, the Alcohol and Drug Abuse Prevention Module was one of the leading services needed for youth in the community. A twelve-session module is used to teach problem-solving and decision-making skills as they relate to substance abuse; the effects of substance abuse on the individual and on the community; various treatment modalities and community resources. Five peer counselors are selected among those participants who complete the entire module and successfully pass a post-test. They are required to make presentations to various groups in the community

and are paid for ten hours of work each week. They are also expected to complete two community service projects each month.

The Body Awareness Resource Network (BARN) Computer Program: This is a nationally tested module that teaches computer skills and healthful lifestyles to adolescents. The BARN system provides information on alcohol and other drugs; body management; human sexuality; smoking; stress management; AIDS; and teen health resources. The program is composed of a holistic health curriculum that promotes literacy skills, reading, and problem-solving. Youth have the opportunity to play computer games while spelling out their personal feelings about health issues and problem-solving. The BARN system was developed within the College of Engineering, University of Wisconsin-Madison, and was funded by a grant from the W.K. Kellogg Foundation.

Recreation, Athletic, and Summer Olympic Activities: Increasing and sustaining male participation in IHAF activities are two of our major goals. Basketball, baseball, karate, and Summer Olympics are used to motivate male participants. Recreational and athletic activities serve the purpose of enhancing the participants' physical well-being, while providing an attractive basis from which other program objectives can be advanced. These activities also promote group cohesion, sense of community, and other positive attitudes on which the IHAF program is based.

Hypotheses

The IHAF program is designed to evaluate both the overall outcome of the project and the intermediate goals that are hypothesized as related to reducing teen pregnancy.

The hypotheses are:

(1) A comprehensive program that enhances future life options and addresses substance abuse, unemployment, and school achievement as well as providing education and access to contraceptives will reduce the rate of teenage pregnancy either by increasing the use of contraception or by reducing the frequency of sexual activity;

(2) Youth involved in the program will achieve higher scores on measures of psychosocial maturity;

(3) Youth involved in the program will achieve higher scores on measures of knowledge of pregnancy prevention, substance abuse prevention, and job skills;

(4) Youth involved in the program will develop stronger attitudes and values conducive to delaying pregnancy (e.g., positive attitudes toward contraception or delaying sexual activity);

(5) Youth involved in the program will develop a more positive attitude and positive expectations toward the future.

Evaluation

The primary method of evaluating the impact of the program is a longitudinal, quasi-experimental study. Youth are tested annually at two intervention sites and at two comparison sites. Youth between the ages of 10 and 17 complete a survey that includes the Minnesota Adolescent Health Survey[21]; the Psychosocial Maturity Inventory[22]; a measure of sexual and contraceptive attitudes and values adapted from the suggested measures of the Data Archive on Teenage Pregnancy and Teenage Pregnancy Prevention Programs[23]; an inventory of knowledge about contraception, sexuality, substance abuse, and job skills; the Piers Harris Self-Concept Scale for Children[24]; and an assessment of youth acceptance of the Nguzo Saba Principles.

An additional method of evaluation is used to assess the impact of each of the modules. Youth are tested before and after the presentation of each module to measure attitudes, knowledge, decision-making, and other variables that the module is expected to change.

Data analysis

The initial enrollment in IHAF is defined as those who completed a baseline survey. From 1987 to 1989, 567 youth completed this survey at two intervention sites and 431 completed the survey at the two control sites. Currently, the analysis of the project does not allow for reporting the effectiveness of more than one of the modules. The Substance Abuse Prevention module significantly improved attitudes, knowledge, and decision-making skills in the 14 youth who participated regularly in the module. Five peer counselors were selected from this group based on their knowledge of the material covered in the class and on their attendance records.

Issues in evaluating IHAF

While an in-depth discussion of all the issues considered in evaluating the IHAF program lies beyond the scope of this paper, three major issues deserve some attention.

Attrition rate: In the 12 months between the baseline survey and the second phase of data collection, which is in progress, there has been a 47.6 percent attrition rate from the two intervention sites. Some youth who may have actively participated in the program have moved out of the housing projects and are no longer available for follow-up. This problem reduces the sample size and the power of the statistical analyses. It may also lead to an inaccurate portrayal of the effect of the program. The usual method for dealing with individuals who move during a research study is to ask for the names, phone numbers, and addresses of several individuals who will always know where the study participant lives. This information is frequently difficult to obtain. Many participants have difficulty identifying three individuals who will always know

where they are. In addition, those who are identified are often as transient as the study participant.

Selection bias: Those who choose to participate in the program may represent highly motivated youth who are less at risk than those who do not voluntarily attend IHAP programs. Such a bias may work in favor of a positive evaluation of the program, but the results will not accurately represent the effectiveness of the program. Recruitment may need to be directed specifically at youth who are at the most risk, because of school failure, "deliaquent" behavior, or their own status as a product of teenage pregnancy. Most of the youth living in the housing projects are considered high-risk due to their lower socioeconomic status. But some are at greater risk than others.

Participation rates: Different youth may participate to different degrees. It is important to have in place some mechanism for evaluating the project in relation to the level of participation of the individual. For example, we need to know whether it is necessary for the youth to participate in all activities or merely one or two programs to produce a desired effect. This process requires a large amount of paperwork and a commitment to completing such paperwork by those who provide services.

Future activities

Our immediate goal is to successfully implement the second phase of this seven-year longitudinal program. This should afford a sufficient database to provide a valid evaluation of the intervention. If these efforts do indeed prove worthy of replication, we will then attempt to disseminate the program on a wider basis.

However, regardless of the outcome of the intervention, we plan to establish a national database on inner-city high-risk youth and their families, using the needs assessment measures described earlier in the manuscript. Planning is underway with officials of the Student National Medical Association (SNMA), the student arm of the National Medical Association[5], to carry out this national effort. SNMA has 130 chapters, one in every medical school with the United States; two SNMA national officers are currently enrolled at Meharry Medical College. The development of a national database will be useful not only in and of itself, but necessary if the IHAP intervention proves worthy of replication.

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1578

AlF$_4^-$ ACTIVATION OF K^+(^{86}Rb) FLUXES IN A HUMAN SUBMANDIBULAR EPITHELIAL CELL LINE. Lauren Patton, Valerie Horn, Sonya Taylor and Robert Wellner. National Institute of Dental Research (CIPCB), Bethesda, MD 20892.

Treatment of HSG-PA cells with the G-protein activator AlF$_4^-$ (10 mM AlCl$_3$ + 10 mM NaF) increases both ^{86}Rb influx and efflux in a manner similar to that resulting from carbachol (muscarinic agonist) or W7 (calmodulin antagonist) treatment. The time dependencies of the AlF$_4^-$ stimulated ^{86}Rb fluxes are slower and more sustained than those resulting from 10^{-4} M carbachol or 5 µM A23187 stimulation, and markedly differ from 50 µM W7 stimulated fluxes as well. Low concentrations of NaF (≤ 1mM) and all concentrations of AlCl$_3$ tested (5-100 µM) fail to stimulate ^{86}Rb fluxes. NaF concentrations of 5-10 mM stimulate both ^{86}Rb fluxes, and these stimulations are increased further by AlCl$_3$ (≥10 µM). Both AlF$_4^-$ stimulated ^{86}Rb fluxes are blocked by the K^+ channel blockers quinine and charybdotoxin, which also block carbachol, A23187 and W7 stimulated fluxes. Both stimulated fluxes are partially blocked by phorbol myristate acetate (protein kinase C activator), but not by a phorbol ester analogue which fails to activate protein kinase C. Both stimulated fluxes are insensitive to atropine (muscarinic antagonist), tetraethylammonium chloride (K channel blocker) and pertussis toxin (ADP-ribosylates a G protein in HSG-PA cells). These results suggest that activation of one or more pertussis-insensitive G-proteins results in activation of quinine and charybdotoxin-sensitive K channels in HSG-PA cells.

1580

IN VIVO AND IN VITRO EFFECTS OF 19-NORTESTOSTERONE ON Na^+, K^+ -, Mg^{++}-DEPENDENT AND INDEPENDENT Ca^{++}-ATPases IN GUINEA PIG TESTIS. S. Mukherjee, H.H. Foster and S. K. Das. Meharry Medical College, Nashville, TN 37208.

19-nortestosterone hemcyphenylpropionate (Anadur) has been considered to be an effective male contraceptive drug. The exact mechanism by which this drug elicit effects on sperm motility and fertility is not clearly known. The purpose of the present study was to investigate in vivo and in vitro effects of this drug on the sperm motility as well as the activity of Na^+,K^+- and both Mg^{++}-dependent and independent Ca^{++}- ATPases in guinea pig testis. The drug was administered intramuscularly (0.5 - 4 mg /kg), daily for 7 to 60 days. The density of mature sperm as well as its motility was decreased in vas deferens, ejaculatory ducts and prostatic urethra due to the drug treatment. Furthermore, this drug caused a significant inhibition in the activity of all the ATPases in a dose dependent manner in the microsomal fraction of testis. However, under in vitro condition, this drug did not have any significant effect on the Mg^{++}- independent Ca^{++}- ATPase while inhibiting the activity of the other two ATPases. (Supported by grants from the Lalor Foundation and NIH-GM-08198).

1582

RELATIVE INSENSITIVITY OF MADIN-DARBY BOVINE KIDNEY (MDBK) CELLS TO Na^+/K^+-ATPase INHIBITORS

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In our efforts to isolate the endogenous, long acting natriuretic factor, which may be an inhibitor of the Na^+/K^+-ATPase, we have tested a variety of known Na^+/K^+ ATPase inhibitors and possible candidate model steroids of the factor. These compounds were incubated at various concentrations with MDBK cells (ATCC No. CCL22), a renal epithelial cell

ASK the
PERINATOLOGIST
Newsletter

VOL. 1, NO. 1 Department of Obstetrics and Gynecology, Meharry Medical College, School of Medicine FALL 1991

Sickle Cell Anemia Not A Risk For PTL

by Henry W. Foster, Jr., M.D.
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Q. Does uncomplicated sickle cell anemia increase the patient's risk for preterm labor?

Should sickle cell trait be considered a deterrent to pregnancy on the basis of increased risk to the mother?

There are no documented studies showing an increased risk for preterm labor or any increase in either maternal or perinatal mortality in patients who carry the sickle cell trait, i.e., who are heterozygous (Hb AS). There are, however, some patient management issues that are different from those in the general population that warrant special consideration. Patients with sickle cell trait require competent and compassionate genetic counseling because they are at risk for producing offpring with sickle cell disease (Hb SS). It is important for these trait patients to know that their genetic condition most likely occurred as a spontaneous mutation in response to the malaria parasite Plasmodium falciparum. Such an explanation provides patients a rationale for why their condition exists, which helps decrease the stigmatization they often feel. Audiovisual material is useful in explaining the genetic implication of the disease. Genotype charts displaying percentage inheritance odds are particularly useful. The most frequent risk is the trait-by-trait (HB AS/AS) mating; it carries a 25% chance of producing a child with the sickle cell disease (Hb SS), a 25% chance of one with no S hemoglobin (Hb AA) and a 50% chance of one with the trait Hb AS). When either parent has the disease (Hb SS), there is no chance for any offspring to escape the inheritance of S hemoglobin, irrespective of the genotype of the other parent.

Those pregnant sickle cell trait patients at risk for producing an offspring with sickle cell disease (Hb SS) now have the option of antenatal diagnosis using amniocentesis or chorionic villus sampling for restriction enzyme analysis of fetal genomic DNA. This ability to ascertain the fetal hemoglobin status in utero extends our capacity to provide genetic counseling. Such capability affords the option of pregnancy termination, as is available with other genetically propagated diseases such as Down syndrome, Tay-Sachs, neural tube defects, etc.

Pregnant patients with sickle cell trait have increased morbidity as it relates to the urinary tract. Asymptomatic bacteriuria is reported in 25% of these patients (8% in the general obstetric population), and pyelonephritis in 7% gross hematuria, and over time patients with trait may develop hyposthenuria — the inability to concentrate urine. Both sickle cell trait and sickle cell disease patients should have urine cultures and sensitivity studies done in each trimester. Positive cultures should be treated with appropriate antibiotics for 3 weeks or until negative.



This newsletter answers questions most frequently asked of the perinatologist. It has been published with the generous contributions of various perinatologists or specialists in an area of perinatal medicine from around the country. The editor and department appreciate their participation.

WCH

has twins. I have another patient who has had a previous preterm birth at 32 weeks gestational age. What is the perinatologist's opinion about giving both of these patients prophylactic terbutaline? In this way I could prevent the patient from going into preterm labor and lengthen her gestation period.

A. There is no evidence that prophylactic use of a tocolytic agent such as terbutaline or ritodrine or oral magnesium will prolong pregnancy. In fact, there is evidence that the prophylactic use of a beta mimetic agent such as terbutaline could be harmful, particularly with the patient developed preterm labor and required tocolytic therapy. The oral use of the beta mimetic would cause down regulation of the receptors. Then when beta mimetic therapy was instituted as therapeutic tocolytic therapy the agents would not be effective. Several studies have shown prophylactic use of beta mimetic therapy in twin gestations is not efficacious. Most perinatologists would caution against the prophylactic use of tocolytic therapy in any form. Instead, it would be wise to educate the patient about early signs and symptoms of preterm labor, recognizing uterine activity, and informing her healthcare provider about these early signs and symptoms. Home uterine monitoring, especially in the patient with increased risk factors such as a multiple gestation has been shown helpful, but prophylactic tocolytic therapy is not.

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Q. *How do you determine the dose of terbutaline for a patient who is to use the terbutaline pump?*

What is "patient specific dosing"?

How can knowing the pharmacokinetics help in prescribing the terbutaline pump?

A. In order to determine the dose of terbutaline for the pregnant patient should be designed. This may be achieved by applying clinical pharmacokinetics. The objectives of clinical pharmacokinetics are two-fold:

1. An optimum drug concentration at the receptor site must by achieved to produce the desired therapeutic response.
2. The drug's adverse or toxic effects should be minimized.

Pharmacokinetics in the pregnant patient include absorption, distribution, metabolism and an elimination profile. The pregnant patient's physiological condition must be considered, including such characteristics as gestation age, height, current weight, prepregnant weight, cervical status and nutritional status. Pathophysiological conditions (e.g., renal disease, liver disease) may affect terbutaline pharmacokinetics in the patient as well. Other medications may modify the predicted activity of terbutaline also.

Terbutaline's target concentration (the desired plasma or serum drug concentration for optimal therapeutic effect) and the therapeutic window must be considered when the dosing regimen is made.

Each patient has different pharmacokinetics parameters. A small woman with a singleton gestation should not require the same terbutaline dosage that an average woman with a multiple gestation. The safety and efficacy of terbutaline can be maximized by understanding the maternal clinical pharmacokinetics.

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Q. *A patient informs me at 10 weeks gestational age that she has been using cocaine since the beginning of her pregnancy. How should I counsel this patient?*

What advice could I give her regarding her substance abuse and it's effect on her pregnancy?

What community resources should I try to find which may be able to help her?

sent in 10 to 20 percent of all pregnancies in this country. Cocaine is the most commonly used drug and by that standard alone is responsible for a larger number of affected newborns. This patient should be warned that continued use starting from such an early stage puts her unborn child in great jeopardy of birth defects, growth retardation and developmental dysfunction. This should be done in a compassionate manner.

She should be advised to immediately discontinue cocaine use. Additionally, she should be warned to also stop cigarette smoking, and the use of alcohol or other drugs even in small amounts.

Community resources that provide in-patient and/or out-patient detoxification with intensive outpatient follow-up should be located. Many public health departments are active in providing nutritional supplements and nurse case workers to assist the mothers and monitor the home environment.

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Your letters, questions and comments are welcomed.

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fasting blood sugar and/or elevated post prandial blood sugars on intravenous Ritodrine, how should she be treated?

A. If the post prandial BGs exceed 250 mg/dl, insulin therapy should be started, intravenously at first, followed by a split mix of regular and intermediate human insulin and a diabetic diet. If more moderate hyperglycemia persists beyond 24 hours, the same regimen should be followed, starting with a total dose of 0.7-1.0 u/kg. If the Ritodrine or terbutaline therapy is discontinued and the hyperglycemia (PPBG > 130 mg/dl) disappears, the insulin therapy can be stopped.

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Q. *What is the role of home uterine activity monitoring in the prevention of preterm birth in twin gestations?*

A. Multiple gestation is the highest risk condition for early delivery among women with physical or historic characteristics making them more likely to delver at less than 37 weeks. Until recently many different approaches such as bed rest, prophylactic tocolytics, cerclage, etc. have been tried and have not prolonged gestation in these pregnancies. Using the comprehensive system of home uterine activity monitoring to detect contractions as well as intensive perinatal nurse surveillance during daily phone contact (for signs and symptoms suggestive of early labor) the rate of preterm births among women with multiple gestations has been decreased when compared to those receiving standard high-risk care. This monitoring should begin at 18-20 weeks and be discontinued when the patient reaches 37 weeks. Assessment of the cervix should be performed every 1-2 weeks. Monitoring is carried out in the home for one hour in the evening and one hour the is then placed to the Tokos Perinatal Nursing Service and the data transmitted by phone to be evaluated by the Special Care Nurse who also asks questions about signs and symptoms indicative of preterm labor. When there are ≥ 4 contractions/hour an additional hour of monitoring is performed (after oral hydration) in the lateral recumbent position. If any symptoms are present or if contractions exceed four per hour on a remonitor strip, the patient is asked to see her physician in the office or int eh Emergency Room. Utilizing such a comprehensive system is one way that the number of preterm gestations can be reduced in those women who have multiple gestations.

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Q. *What is the role of antibiotic therapy in the prevention of preterm labor? Should patients at increased risk for preterm labor have their cervix cultured and when positive, treated with antibiotics?*

A. Despite advances in perinatal medicine, prematurity remains the leading cause of neonatal morbidity and mortality. There is a growing body of biochemical and clinical evidence that infection contributes directly or indirectly to 40-60% of preterm deliveries associated with preterm labor or premature rupture of the membranes.

This proposed link between infection and prematurity suggests that antibiotic therapy may be useful in preventing the occurrence of preterm labor.

Today there have been only two randomized clinical trials in which nonbacteriuric women have been treated prenatally with either antibio-tics or placebo.

In 1971 Elder, et al,[1] reported on a prospective randomized study of treatment with tetracycline of bacteriuric and nonbacteriuric pregnant women. They noted that nonbacteriuric prenatal patients treated with cidence of low birth weight than placebo treated nonbacteriuric women (6.8% vs. 15.9%).

In 1987 McCormack, et al,[2] tested the theory that genital mycoplasma were related to preterm birth. They randomized non bacteriuric pregnant women with positive vaginal cultures for M. hominis or U. urealyticum to receive clindamycin, erythromycin or placebo. These investigators observed that treatment with clindamycin and erythromycin in the second trimester had no effect on the prevalence of low birth weight. However, erythromycin therapy in the third trimester, compared with placebo, was associated with a lower percentage of infants with LBW (<2500gms) 3% (2/64) vs. 12% (10/84). Both the LBW infants in the erythromycin group with IUGR, while in the placebo group, six were IUGR and four were preterm neonates. If this information is taken in account, erythromycin treatment does not reduce the prevalence of preterm birth (0%[0/64] vs. 5% [4/80]).

Based on the above information, the role of antibiotic therapy in the prevention of preterm labor can not be established. Neither erythromycin nor tetracycline could be considered adequate or even reasonable treatment for the wide range of organisms that have been implanted in premature labor. Recolonization, the presence of nonsensitive microorganisms or even the overgrowth of resistant strains seriously limits the prospects for prophylactic antibiotic treatment even if an association between microorganisms and premature labor is established.

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Q. What is the role of oral magnesium in the treatment of preterm labor?

Which magnesium preparation do you use and at what dosage?

A. Oral magnesium has been utilized at our institution for 6 years. After successful tocolysis with parenteral magnesium sulfate the patient is given magnesium gluconate 2 grams every 2-4 hours. This dose causes a small increase in serum magnesium within the normal range.[1] Therapeutic levels of 5 to 7 mg/dl are not achieved as with intravenous Mgso4. Gastrointestinal side effects are related to the amount of elemental magnesium presented to the gut and smaller, more frequent dosages are tolerated better. There is no difference in the effectiveness of the different magnesium preparations. The effects are related to the amount of elemental magnesium given. A 500 mg tablet contains 23 mg of elemental magnesium. A 140 mg tablet of magnesium oxide contains 85 mg elemental magnesium. In small series of patients magnesium has been compared to the beta agonist.[2,3] The recurrence of preterm labor has been similar to the beta agonist and side effects have been less. Magnesium gluconate is much cheaper than either ritodrine or terbutaline. Initial reports of prophylactic magnesium administration are encouraging, but not all investigators have found it to be beneficial.[4,5]

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RESEARCH REPORTS

ARTICLES

Accommodating to Restrictions on Residents' Working Hours

HENRY W. FOSTER, Jr., M.D., and VICKI L. SELTZER, M.D.

Abstract—In 1988, New York became the first state to implement regulatory measures limiting housestaff work hours. Because restrictions on residents' work hours will have such profound and far-reaching implications for how obstetrics and gynecology residencies are conducted, the Council on Resident Education in Obstetrics and Gynecology (CREOG) requested that a survey be conducted to solicit information from program directors of U.S. obstetrics and gynecology residencies who had already begun to alter their call schedules. Two hundred and ninety-six programs were contacted, and representatives of those that had implemented changes were requested to respond. Eighty-two responses were received; 26 of these contained info: mation that could be collated. From these 26 responses the au thors have structured a prototypic call schedule and presente its application. A key feature necessary to implement the ne type of schedule is the use of a night float system. It is conclude that changes can and will be made by obstetrics and gynecolog residencies. Creative scheduling, as described in this article, : essential and will facilitate the task; however, the current stan dards of education and patient care will be difficult to maintai without additional economic and human resources. *Acad. Mec* 66(1991):94–97.

On June 9, 1988, the New York State Hospital and Planning Council adopted regulations to limit housestaff working hours. These provisions have subsequently been approved by the health commissioner; the first provision, which limited resident emergency coverage to a maximum of 12 consecutive hours, was enacted on September 1, 1988. The precipitating event leading to these regulatory changes was the death in 1984 of 18-year-old Libby Zion a few hours after she was admitted via the emergency room of a New York City hospital. It was alleged by her father, a writer for the *New York Times*, that inadequate care provided by overworked and unsupervised house staff contributed to her death.[1]

To help bring about this reform in the state of New York, the Ad Hoc Advisory Committee on Supervision of Residents' Working Conditions and Emergency Services was established.[2] This committee, whose members were all physicians with backgrounds in academic medicine, is known as the Bell Committee. The salient issues contained in the New York regulations that resulted from the committee's activities are (1) a maximum 80-hour week (averaged over four weeks, including moonlighting), (2) a 24-hour maximum duty assignment, (3) a mandatory eight hours off (following the maximum assignment), (4) a 12-hour maximum daily emergency room coverage, and (5) at least one 24-hour period of scheduled nonworking time each week.

Other states besides New York that at the time of this study had begun to formally address the issue of setting limitations on residents' work hours were California, Hawaii, Pennsylvania, Massachusetts, and Illinois. As c late 1990, no state including Ne York had successfully enacted legisla tion restricting residents' work hours instead, regulatory measures hav been adopted. Even before the regula tions in New York were adopted the Executive Council of the Associ ation of American Medical College had published recommendations re garding residents' supervision and hours.[3,4] In the discipline of obstetric and gynecology (ob-gyn), som aspects of the subject were explored in 1986 and 1987.[5,6] Also, residen physicians themselves have begun to seek reform on this issue.[7–9]

Method

Because restrictions on residents work hours will have profound and far-reaching implications for how ob-gyn residency programs can be conducted, the Committee on Resident Education for Obstetrics and Gynecology (CREOG) asked that information about programs' responses to restrictions be gathered from program directors who had begun to grapple

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with this problem. Two hundred ninety-six U.S. ob-gyn program directors were polled; only those who had altered their call schedules to meet current or anticipated restrictions were requested to respond. Eighty-two responded, and of these, 26 provided information indicating the various approaches that had actually been put into place to adapt to restrictions on residents' work hours. This was felt to be a good response rate, since only those programs that had actually implemented changes were requested to respond. However, the 56 other programs that responded provided various comments and reactions on the subject, although they had not actually implemented any schedule change. Twelve (46%) of the 26 responses indicating definitive program changes came from the Northeast. The distribution was as follows: New York, four programs; Massachusetts, three programs; and New Jersey, Connecticut, Massachusetts, Rhode Island, and Pennsylvania, one program each. There were three programs (12%) from the West: one each in California, Colorado, and Oregon. The remaining 11 responses (42%) had a varied geographic distribution: Michigan, three programs; and one program each for Ohio, Indiana, Minnesota, Kansas, North Carolina, Oklahoma, Tennessee, and Texas.

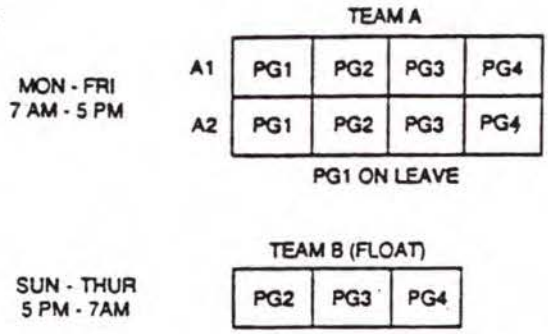


Figure 1. **A prototype of a call schedule for a program of 12 residents, three per year in a four-year program. At any given time, eight of the 12 residents provide day and weekend coverage, three residents provide the night float coverage, and one resident is off service. (Note: "PG1" means "postgraduate year 1.")**

Results

No single schedule will be applicable to all programs. Too many local imperatives and variations exist. However, there are three basic components that the data show are deemed essential for any nontraditional call schedule. These components are (1) day coverage, (2) night coverage (float), and (3) weekend coverage. In order to provide program directors a useful basic call schedule format to which they can apply their necessary modifications, the authors have created a prototype call schedule for a program of 12 residents — three per year in a four-year program. This prototype, presented in Figure 1, contains the three basic components necessary — day coverage, night coverage (float), and weekend coverage. In this working prototype, at any given time, eight of the 12 residents provide day and weekend coverage (Team A, subdivided into Team A1 and Team A2); three residents provide night float coverage (Team B); and one resident is off service at any given time. This arrangement, which provides for having a resident off service, allows each resident four weeks off annually, a total of 48 weeks for all residents, for such activities as vacation, sick leave, educational activities, and maternity leave. However, this aspect would require modification if more than four weeks of total leave time were offered.

To help clarify this rather complex process, this nontraditional schedule is presented in block diagram form, depicting one week's coverage (Figure 2). In this block diagram prototype, the participation of Team B (the float or night coverage) is straightforward; call schedule begins at 5:00 p.m. and ends at 7:00 a.m., five days a week starting on Sunday evening and ending at 7:00 a.m. Friday morning. Team B is then off each Friday and Saturday and returns to work at 5:00 p.m. on Sunday. This arrangement constitutes a 14-hour work day or a

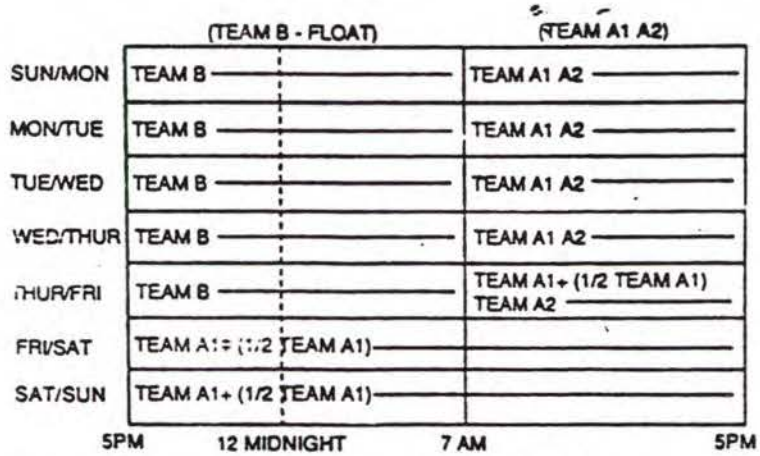


Figure 2. **A prototype of a nontraditional call schedule for one week of coverage. In this schedule, residents would spend a total of four months in Team B on the night float and eight months in Team A covering days and weekends. (See the text for an analysis of this schedule.)**

70-hour work week. In this proposed prototype, it is suggested that Team B (float) cover for a period of two months, twice per year. However, alterations in this regard can be made. It was indicated by program directors who had used such a system that about ten days are needed to reestablish the resident's circadian rhythm; hence, it seems logical to have as few changes in the resident's schedule as possible. Therefore, for the year, residents would spend a total of four months on the night float and eight months on Team A covering days and weekends.

As shown in Figure 2, participation of Team A (A1 plus A2) during the week is straightforward for Mondays through Thursdays; however, beginning at 7:00 a.m. on Friday, the weekend coverage is more complex. Team A1 is responsible for weekend coverage, while Team A2 is off for the weekend; accordingly, Team A2 simply starts its last working day for the week at 7:00 a.m. on Friday, and completes its work day at 5:00 p.m. on Friday, and is off for the weekend, to return again at 7:00 a.m. on Monday. However, Team A1, whose members are responsible for weekend coverage (in this diagram), must be further subdivided into teams A1† and A1‡ (two members each). Team A1†, along with A2, comes to work at 7:00 a.m. on Friday and works until 5:00 p.m.; Team A1‡ comes to work at 5:00 p.m. on that Friday and works a 24-hour shift until 5:00 p.m. the next day. At 5:00 p.m. on Saturday, Team A1†, whose members had gone off duty at 5:00 p.m. the previous day (Friday), returns at 5:00 p.m. Saturday to work a 24-hour shift that ends at 5:00 p.m. on Sunday, the time at which Team B (float) takes over, thus completing the week's cycle.

Last, the authors devised the following monthly schedule that indicates how a single resident on Team A would function in the Figure 2 schedule while not violating any of the constraints of the New York regulations.

Week 1: From Monday through Thursday, the resident would work 16 hours; Friday and part of Saturday would contain 24 hours of work; and the rest of Saturday and all of Sunday would be time off.

Week 2: From Monday through part of Friday, the resident would work 50 hours; the rest of Friday and all of Saturday and Sunday would be time off.

Week 3: From Monday through part of Friday, the resident would work 50 hours; the rest of Friday and part of Saturday would be time off; and the rest of Saturday and all of Sunday would contain 24 hours of work.

Week 4 (This is the same schedule as in Week 2): From Monday through part of Friday, the resident would work 50 hours; the rest of Friday and all of Saturday and Sunday would be time off.

This resident has, therefore, met the hours-limitation requirements contained in the New York regulations. The resident has worked a total of 238 hours for the month, which averages just 59.5 hours per week. In addition, there were no maximum-duty assignments that exceeded 24 hours and there was a period of at least eight hours off between any maximum duty assignment and a contiguous assignment

Discussion

It became clear from collating these data that the challenge was to meet the constraints of restricted resident work hours without (1) decreasing educational standards, (2) decreasing patient access to quality services, (3) increasing the number of residents, (4) increasing the length of training, or (5) increasing costs. It seems unlikely that all of these challenges will be completely met. It will be difficult, if not impossible, to achieve in an 80-hour work week what was previously accomplished in a 100-hour work week. However, through thoughtful and creative scheduling, the negative impact of reduced resident work hours can indeed be lessened.

Ancillary factors will make the successful implementation of a nontraditional call schedule difficult. A small complement of residents makes the exercise most difficult. A 12-member residency program was chosen intentionally as an example, since it presents a greater challenge. All of the numbers given in the example prototypes presented in this article could be doubled in a program that has 24 residents; weekend coverage would then allow for four residents to be on call rather than two, as in the example given for the 12-resident program.

Some other compounding factors are the existence of more than one service site, distant proximity of service sites, reduced attending physician staff, and inadequate commitment by hospital administrators. Various methods of augmentation can help offset these difficulties, although in most circumstances additional financial and human resources will be required. Some of these measures involve the use of family practice residents or other physicians, nurse midwives, nurse practitioners, and physician assistants. In addition, as more residency programs move to providing 24-hour in-house attending physician coverage, some of the difficulties resulting from reducing residents' work hours will be ameliorated. It is apparent that adjusting to the restrictions on residents' work hours is least problematic for programs that have large numbers of residents in a single physical setting, and conversely, is most difficult for small programs, which may have more than one service site. For the latter category, meeting the requirements will be difficult, if not impossible.

In reviewing the information received from these program directors who had begun to change their schedules, and from subsequent discussions with some of them on the subject, it appears at present that these scheduling changes are being driven primarily by the need to meet patients' service requirements. It is essential that attention be given to possible educational deficits that may be created by reducing residents' work hours under certain circumstances. Using the prototype schedule presented in this ar-

ticle, additional formal educational activities can be held during evening hours when the day shift is ending, or in the mornings when the night float shift ends. This arrangement allows those residents on the night float to participate in grand rounds, conferences, seminars, and other educational activities.

Clearly, there is a movement developing to effect measures to prevent excessive work hours for residents such as the work hours reported from New York, which, of course, are not typical of most ob-gyn programs. However, there is little doubt that such changes will be pervasive and will eventually involve most programs. The information presented here is but a beginning effort to provide direction and stimulate program directors in ob-gyn to begin to think this matter out so they can meet the challenge more effectively.

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The Uses and Value of Autopsy in Medical Education As Seen by Pathology Educators

ROLLA B. HILL, M.D., and ROBERT E. ANDERSON, M.D.

Abstract—A national meeting of pathology educators in 1989 provided the impetus for an exploration of new uses of autopsy in medical education. A month before the conference, the authors sent a questionnaire about the uses and value of autopsy in medical education to 120 persons registered to attend the conference. They used the 93 responses, representing 69 U.S. and Canadian medical schools, as the basis of a workshop on the place of autopsy in future medical education. The present article is a report of the authors' findings from the questionnaire and workshop. They found that the uses of autopsy go far beyond the traditional uses in teaching clinical pathophysiology, clinicopathologic correlation, clinical anatomy, gross and microscopic anatomy of disease, and visual skills. Emphasis was placed on the potential role of autopsy in education regarding legal/judicial proceedings, vital statistics, epidemiologic investigations, and public health, and in the understanding of such complex matters as medical fallibility, medical uncertainty, and grief. These purposes were seen as congruent with current social concerns about the need to reverse the trend toward dehumanization of medicine and physicians. The inability to realize these aims in the face of a precipitous drop in the autopsy rate is discussed. *Acad. Med.* 66 (1991):97–100.

At the beginning of the 19th century, Xavier Bichat, a brilliant young rising star of the Paris school, declared, "You may take notes for twenty years, from morning to night at the bedside of the sick upon the diseases of the viscera, and all will be to you only a confusion of symptoms, . . . a chain of incoherent phenomena. Open a few bodies, and the obscurity will disappear."[1] At that time, it was only in a few medical capitals of Europe that the value of autopsy in medical education was beginning to be understood. Sixty years later, it was easier to say, with Samuel Wilks at Guy's Hospital, that "pathology is the basis of all true instruction in practical medicine."[2]

Somewhat later, in the United States, autopsy came to be recognized as an essential component of medical education. The Johns Hopkins paradigm, introduced late in the 19th century, included an extensive autopsy experience, and after the Flexner report in 1910, this approach was quickly adopted throughout the country. As a consequence, the autopsy room became the intellectual center of the "modern" teaching hospital—a place where students and their teachers all came to learn, to profit from their errors, and to experience a

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ALIVE AND WELL?

A RESEARCH AND POLICY REVIEW OF HEALTH PROGRAMS FOR POOR YOUNG CHILDREN



NATIONAL CENTER FOR CHILDREN IN POVERTY

COLUMBIA UNIVERSITY
SCHOOL OF PUBLIC HEALTH

Foreword

Children in the United States should not be living in poverty today, but they are. The poverty rate for children under six is 23 percent—the highest of any age group in our nation. This is unacceptable. According to data from the U.S. Bureau of Census, 31.5 million people were classified as poor in 1989, as determined by a family's pretax income. Strikingly, of this number, 5.1 million were children under the age of six.

This report on the health problems of poor young children is unique. It is the first comprehensive overview and assessment of the literature that has appeared over the past decade concerning policies and programs that address the health needs of this vulnerable population.

The author recognizes the need to start viewing children and their families in poverty in a different way. We spend over 11 percent of our gross national product on health, and while we clearly do care about our children, we must increase this concern and become more efficient and resourceful in our problem-solving. In the past we have been reactive. We must become more proactive. We must define and develop comprehensive approaches that aid young children and their families during the early years of family formation. The emphasis must highlight prevention, access to quality services and timely and appropriate utilization, and a continuity of health care that contributes to family stability and better outcomes for children's lives.

The sponsor and author of this study clearly recommend a nonremedial approach to child health problems. The monograph has been compiled by combining scientific knowledge and social sensitivity. The text describes the extent to which the health of poor children is worse than that of nonpoor children, and it examines the effect of poverty and its environment on health status and how poor families use health services. It also reviews available public programs and the new policies that are needed. The information contributes insights and direction for federal and state policymakers, health care providers, and public policy advocates.

A debt of gratitude is owed to the author of this work and the National Center for Children in Poverty and its funders for making the publication possible. The volume should remind us of pressing issues and the millions of innocent infants and children whose lives and safety are affected daily by the lack of sufficient attention to their condition. It should call us to commit ourselves to decades of effort to address their needs and to prepare them for productive futures.

January 1991

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R=95%

Graduate Education

Resident scheduling: Night float programs

Vicki Seltzer, MD, Henry W. Foster, Jr, MD, and Myron Gordon, MD

Obstetrics and gynecology residency programs have traditionally involved long hours in the hospital. In recent years, in an attempt to determine whether work hours could be reduced while at least maintaining resident education and patient care, many program directors have instituted night float systems. In New York State, these systems must adhere to rigid hospital code requirements (limiting total hours worked and with specific mandates regarding time away from the hospital); in other areas, these requirements are not as limiting. At the request of the Council on Resident Education in Obstetrics and Gynecology, residency program directors and residents in the United States and Canada were sent a survey regarding whether they had a night float program, how it was structured, and what changes it was perceived to have caused. Responses were received from 193 program directors (65%) and 302 residents. Major differences were noted in the structure of the programs within New York state compared with those outside the state. In New York, 63% of the programs had residents in all 4 years participating in the night float; this was true for only 10% of the programs outside New York. In New York state, the programs were required to adhere to state hospital code requirements limiting hours on duty and mandating the specifics of time off, whereas the programs outside New York did not necessarily adhere to these restrictive requirements. Twelve characteristics were evaluated regarding changes that were perceived to have occurred as a result of the night float program. All were statistically significantly more positive in the night float systems outside New York state; within New York, only one characteristic was rated as improved as a result of the night float system. We conclude that the night float system is perceived as a potentially important innovation in improving resident education and patient care in obstetrics and gynecology; however, the system is more likely to be considered successful when flexibility is permitted. *(Obstet Gynecol 77:940, 1991)*

In 1988, the Council on Resident Education in Obstetrics and Gynecology (CREOG) began to focus on innovative scheduling for resident education in obstetrics and gynecology, with particular emphasis on night float systems. In most obstetrics and gynecology programs, this term is used to describe a schedule in which one resident or a group of residents is slated to be present during most of the evening and night shifts but is not scheduled to be present during the day. This reduces or eliminates the need for daytime residents to remain in the hospital during the evenings and nights.

Approximately 13% of obstetrics and gynecology residency programs in the United States are in New York state, and as of July 1, 1989, these programs must comply with changes in the hospital code limiting resident work to 80 hours per week (averaged over 4 weeks, including moonlighting), a 24-hour maximum duty assignment, a minimum of 8 hours off following such assignment, and a minimum of one continuous 24-hour period off each week. This system requires innovative scheduling. To help the programs in New York state develop schedules meeting these requirements while preserving (or even enhancing) high-quality patient care and excellent resident education, and to help programs in other states and in Canada to consider these issues, CREOG surveyed all obstetrics and gynecology residency program directors. Based on the responses received, schedules were suggested, presented by one of the authors (HWF) at the 1989 CREOG Program Directors' Retreat, and subsequently published.[1]

Subsequently, CREOG continued to receive inquiries from program directors around the country regarding night float systems and innovative scheduling. Therefore, it was decided that it would be beneficial to assess the current status of night float schedules in residency programs in our discipline throughout the

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Table 1. Residency Program Characteristics for Night Float Survey Responses

	New York state	Outside New York
Average number of residents in program each year	4.5	4.5
Average number of hospitals to which residents rotate	2.7	2.4
Average number of hospitals in which residents take night call	2.1	2.0

United States and Canada, and a second follow-up survey was sent to all obstetrics and gynecology residency programs in these two countries. In addition, because change had occurred so rapidly and dramatically in New York state, one of the authors (MG) sent an additional independent but similar survey to program directors in New York.

Materials and Methods

In late 1989, two of the authors (HWF, VS) sent a questionnaire to all 295 obstetrics and gynecology residency program directors in the United States and Canada. Thirty-seven of these went to programs in New York state and 258 went to programs elsewhere. Four additional copies of the questionnaire were mailed to each program director with the request that they have a few of their fourth-year residents complete surveys. Residents and program directors were asked for demographic data about their programs and about resident scheduling. They were asked whether their schedules included night floats, and if so, to rate on a scale of 1 to 5 (1 = improved; 3 = unchanged; 5 = impaired) several characteristics that may have been affected as a result of the night float system. Responses were sent to the CREOG office, where the data were tabulated and subsequently presented at the CREOG Obstetrics and Gynecology Residency Program Directors' Retreat in July 1990. Additional input was given by program directors at the time of the presentation.

A complementary survey was sent to the obstetrics and gynecology residency program directors in New York state in February 1990 by one of the authors (MG), and these data were also presented at the CREOG retreat.

Statistical significance was tested by two-tailed unpaired Student t test and by χ^2 analysis.

Results

Responses were received from 26 New York program directors (70%) and 167 other program directors (65%). Although we requested a response even if the program did not have a night float system, we postulate that in some instances, we did not receive a reply because there was no night float. In addition, of the questionnaires distributed to fourth-year residents, 42 responses were obtained from New York state, 243 from residents representing 40 other states, and 17 from Canada.

Table 1 lists the characteristics of the programs that responded, comparing those within New York state with those outside. In general, the average size of the program, number of hospitals to which the residents rotated, and number of hospitals in which the residents took night call had a similar distribution. However, substantial difference was found in the night float schedules. In New York state, 63% of the programs had all 4 years of residents participating in the night float system, whereas outside New York, only 10% of the programs used residents from all 4 years. Based on χ^2 analysis, these percentage differences are highly significant ($t = 76.7$, $P < .0001$). Forty-one percent of the programs outside New York state had residents from only a single year participating in the night float system (most commonly PGY 2s or 3s), and 29% had only 2 years of residents participating (usually PGY 1s and 2s or PGY 2s and 3s).

The program directors were polled about this major difference in night float structure at the 1990 CREOG Residency Program Directors' Retreat (representing 180 program directors). The nearly unanimous opinion was that this difference occurred because the New York state programs had devised a night float system to meet the very rigid requirements of the hospital code 405 regulations (while also attempting to improve patient care and resident education), whereas those residencies outside New York with night float systems had structured programs directed primarily at improving resident education and patient care and were not concerned about meeting rigid health code requirements regarding hours worked. Those programs outside New York with night float systems were generally not in strict compliance with the New York hospital code 405 regulations, although implementation of the night float systems had frequently decreased the number of hours worked per week.

Table 2 summarizes the responses of program directors regarding 12 characteristics that could be affected by the night float system. For all 12 characteristics, the perceptions of the respondents in New York state were less favorable than those of respondents from outside New York.

Table 3 lists the responses received from the survey sent to residency program directors in New York state. This survey was sent 7 months after implementation of

Table 2. Perceived Results of the Night Float System

	New York state programs ($N = 66$)	Other programs ($N = 427$)	t	P
Resident surgical experience	3.5	2.6	5.3	<.0001
Resident obstetric experience	3.3	2.1	6.3	<.0001
Resident ambulatory care experience	3.2	2.7	3.19	<.0008
Experience with other rotations (eg, oncology, endocrinology, urogynecology)	3.3	2.7	4.46	<.0001
Continuity of care	3.97	2.87	6.16	<.0001
Capability to manage complications	3.4	2.4	6.5	<.0001
Resident attendance at conference	3.5	2.5	4.88	<.0001
Resident reading and studying	3.69	2.2	8.58	<.0001
Residents' satisfaction with program	2.53	1.93	3.35	<.0006
Effect on residents' personal life	3.29	2.28	3.29	<.0006
Expected abilities of residents at completion of program	3.13	2.46	4.26	<.0001
Quality of patient care	3.53	2.07	8.18	<.0001

1 = improved; 3 = unchanged; 5 = impaired.

the new hospital code regulations, and there was a 67% response rate. Although an improvement was noted in residents' satisfaction and alertness, the program directors felt that this had been at the expense of resident education, possibly with some diminution in the quality of patient care, development of a "shift mentality," and decreased faculty satisfaction with resident performance.

Discussion

Residency program directors in obstetrics and gynecology often reevaluate their programs, seeking innovative ways to strengthen resident education while maintaining or enhancing the quality of patient care. One mechanism employed has been the night float system as an alternative to traditional resident scheduling.

The information obtained in this survey suggests that the night float system can have a positive impact when the program director is not forced to adhere to restrictive guidelines. The respondents from outside New York state believed that the night float system had improved their programs in all aspects surveyed (Table 2). On the other hand, respondents from New York indicated that the night float system, in conjunction with the requirements for resident scheduling resulting from the hospital code 405 regulations, had a negative impact on all characteristics evaluated except for resident satisfaction (Table 2).

Table 3. Response of Residency Program Directors in New York State

	Increased	Decreased	No change	No response
Residents' satisfaction	46%	17%	25%	13%
Development of "shift mentality"	54%	0%	29%	17%
Faculty satisfaction with resident performance	4%	46%	38%	13%
Quality of patient care	4%	29%	42%	25%
Resident alertness	29%	8%	50%	13%
Resident education	8%	46%	25%	21%

The second survey, sent only to obstetrics and gynecology residency program directors in New York, supported the findings of the resident educators in that state: that the rigid requirements for resident scheduling were perceived as having had a negative impact on resident education and patient care.

To evaluate why the institution of night float systems appears to have had a positive impact outside New York state but a negative impact within the state, it is important to evaluate why these systems for innovative scheduling evolved and how the systems differ in New York.

Residencies in obstetrics and gynecology have traditionally been intense, combining patient care and resident education, with on-duty hours that some consider excessive. Obviously, it would be beneficial to assess whether resident education and patient care could be maintained and perhaps even improved by reducing resident work hours.

During the past decade, it has been suggested that inadequate sleep and fatigue may contribute to resident stress.[2-4] Some night float programs were devised in part to address this issue. Program directors evaluated patient needs, the overall educational program, and the numbers and needs of the residents, and developed individualized programs that would optimally address the various issues within their departments. These programs added flexibility rather than limiting it. As seen from our data, these programs are generally considered successful by both program directors and residents.

The night float systems in New York state appear to have been devised with minimal flexibility because of mandatory hospital code regulations: a maximum of 80 work hours per week when averaged over 4 weeks, no more than 24 sequential hours worked with at least 8

hours off subsequently, and at least one 24-hour period off each week. Program directors could not evaluate educational or patient care needs, or variations in individual capabilities or personal requirements, and modify the residency programs and night float systems accordingly if in doing so they violated any of the code requirements. At the 1990 CREOG Program Directors' Retreat, program directors from outside New York who had successful night float systems indicated that, for the most part, their programs did not comply fully with the New York state requirements. This is the only variable that we could identify by which programs within New York state differed from those outside.

This information represents the early responses of program directors and residents to extreme changes in the structuring of programs based on requirements unilaterally mandated by hospital code. It will be necessary to continue to monitor the situation to determine whether these negative perceptions persist or whether positive adjustments can be made over time. We intend to evaluate the long-term impact of these changes after they have been in place for a few years.

The attempt to remodel resident work hours and to minimize sleep deprivation has been a positive step and, for the most part, night float systems in obstetrics and gynecology residencies throughout the country have been an important and successful innovation. Obstetrics and gynecology residents should be allowed to learn and work in a humane environment conducive to professional and personal growth. Attempting to achieve a balance between educational and service requirements and the personal needs of the resident should be a significant concern. However, just as the rigidity of the old schedules had imperfections, rigid changes, even with good intentions, may also pose problems. The unique attributes and the needs of the individuals and the department should be considered when formulating an optimal resident schedule. Otherwise, the positive aspects of reduced resident work hours and innovative scheduling will be offset by potential deficits in resident didactic and clinical education, as well as loss of continuity and quality of patient care. Although other states have begun to address the issue of resident work hours, we hope that any steps taken will have sufficient flexibility to maximize resident education and patient care, given the variables of each individual program.

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MERGER RECRUITMENT: THE PROCESS, THE EDUCATIONAL IMPLICATIONS

by Henry W. Foster, Jr., M.D., Dean, School of Medicine
andVice President for Health Services Meharry Medical College

As most Nashvillians now know, Meharry has successfully recruited its 74 physicians needed for the merger process — 56 staff physicians and 18 resident physicians.

Recently, I have been frequently asked, "How were you able to recruit such highly qualified physicians in such a short period of time?" It is a fair question and I can assure it did not occur by happenstance. The process was divided into the following three operational phases: 1) awareness, 2) engagement and 3) placement.

The "awareness" phase had as its goal to make known as widely as possible in the best environs our recruitment needs. This included placing ads in national medical journals; sending 1,500 recruitment flyers to the other 125 deans of medical schools; sending letters of solicitation from all of our chairs to all 125 of their counterparts; attendance and advertisement at national medical meetings; and visiting and working closely with Meharry's National Alumni Association. After 6 months, virtually everyone in this country in academic medicine was aware of Meharry's recruitment campaign.

The "engagement" phase began basically when a prospective faculty member made contact with me. The routing sequence was designed such that virtually all correspondences and curricula vitae came to my attention first. Having mutually developed the staffing document and its criteria with city and Vanderbilt officials, I was better positioned to screen the applicants. This initial contact was followed by a detailed letter from me to the inquirer describing Meharry's history, present events attendant to the merger and our aspirations for the future. Once curricula vitae had been screened, they were placed into the hands of the various Chairpersons; most of the subsequent recruiting responsibility then fell to them. During this engagement phase, I cannot stress too strongly how much emphasis was placed on recruitment of spouses. This was viewed as paramount. In addition to aiding spouses who sought employment, information on schools, churches, parks, museums, libraries and yes, shopping centers, was always made available.

The final phase which was the "placement" phase, dealt mostly with the logistics of securing all needed supports for those physicians who had agreed to join our faculty, e.g. moving, selecting schools for children, assistance in locating housing, securing medical licenses, banking facilities, medical liability insurance, hospital privileges, etc. I view it extremely important, in fact absolutely mandatory, to maintain the same level of interest in candidates after they have signed up (placement), as was maintained during the phase of engagement. This level of attention reduces the level of anxiety which, understandably is attendant to any change of venue. During the

whole of this recruitment process, 408 physicians contacted Meharry. It was from this pool that we derived the 56 staff physicians' slots. The pool size was a major determinant as to the high quality of the faculty.

Now, what does all of this mean for Meharry's teaching goals and objectives? Starting with the basic sciences departments, this new cadre of clinical faculty now available will expand on what we have characterized as "clinical correlation." This is the process wherein students are exposed to a "tie-in" of basic and clinical sciences in an effort to bridge that artificial pedagogical gap, that we in academia have erected in an attempt to effect order in teaching.

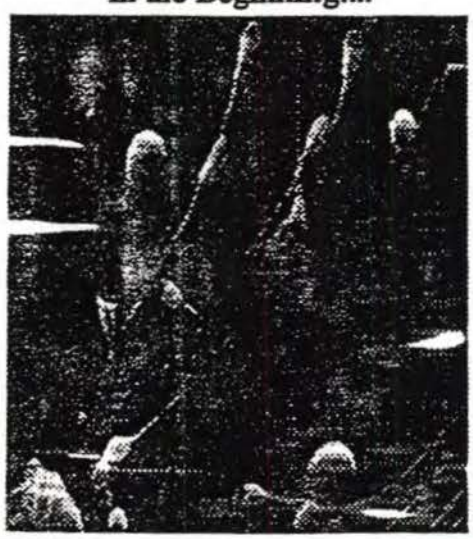
As we address curriculum reform, venture into the realm of Problem Based Learning (PBL), strengthen our board review courses, seek more mentors for our students and enhance our Summer Biomedical Sciences Program, the acquisition of this diverse pool of new faculty for Meharry is most timely. But be reminded that their presence is process; the true measure of the value and effectiveness of these faculty members will be determined by defined outcome measures. Among our most important outcomes for our students are better performance on outside objective examinations, greater success at obtaining residency choices and most important, becoming effective committed members of the health care profession.

The role of these new clinical faculty will be more evident on the clinical side. The improved teaching that will result from having these new faculty will occur in the classroom, as well as in the hospital and in out-patient settings.

In order to help better hone the teaching skills of these new faculty, Richard T. Williams, Ph.D., of the office of Academic Development & Support Services has structured a retreat for this purpose. Twenty to twenty-five medical faculty new to Meharry will participate July 16, 17 and 24, 1993. The retreat is designed to help physicians improve their teaching skills. This interactive program will provide the means by which novice instructors will be able to improve the quality of the decisions that they make about teaching activities in three important areas: curriculum, instruction and evaluation, according to Dr. Williams.

Efforts such as this retreat should strengthen our faculty's teaching ability. If faculty are successful, our students will prosper academically, become superb physicians and will be imbued with the quest for lifelong learning, which is Meharry's ultimate goal for all of its graduates.

In the Beginning....



Workshops of Note

Remember PROBLEM BASED, STUDENT CENTERED LEARNING (PBL)? If so, and if you have an interest in being a group facilitator/tutor, check out the Tutor Training Workshop on June 28-30, 1993 in the Orange Room of the cafeteria. You will get the opportunity to see what being a group facilitator is all about. There will be training on how to keep a group on track, how to handle a student who wants to control the group or a student who doesn't want to talk. There will also be a chance to work with groups of faculty and students. The workshop leaders are Kirk Smith, Biochemistry, Cheryl Hamberg, Library, and Richard Williams, ADSS. For more information and registration call x-5753.

ORIGINAL COMMUNICATIONS

LOW BIRTHWEIGHT IN AFRICAN AMERICANS: DOES INTERGENERATIONAL WELL-BEING IMPROVE OUTCOME?

Henry W. Foster, Jr, MD, D. Johniene Thomas, MSPH, Kofi A. Semenya, PhD, and John Thomas, MD
Nashville, Tennessee

The primary antecedent of infant mortality is low birthweight. Vital statistics data have shown that women of low socioeconomic status, regardless of race, are at greater risk for delivering low birthweight infants; however, prevailing data show that black women of the same socioeconomic status as white women have a twofold higher risk of giving birth to an infant weighing <2500 g and a threefold risk of delivering a very low birthweight infant weighing <1500 g. There is also evidence that intergenerational effects on birth outcome exist. However, virtually all studies of the effect of socioeconomic status on perinatal outcome have been cross-sectional; the effect of sustained intergenerational well-being has not been measured. To address this gap, this study was designed to demonstrate that in an African-American population with sustained high socioeconomic status and equal risk factors, the birthweight distribution and other reproductive outcomes are the same as those for comparable US white populations. Preliminary findings are reported here. (*J Natl Med Assoc.* 1993;85:516-520.)

Key words • low birthweight • very low birthweight • perinatal outcome • socioeconomic status

From the Department of Obstetrics and Gynecology, Meharry Medical College, Nashville, Tennessee. This epidemiological study was funded by the US Department of Health and Human Services, Public Health Service Grant no. MCJ-477008. Requests for reprints should be addressed to Dr Henry W. Foster, Jr, Dept of Obstetrics and Gynecology, Meharry Medical College, Nashville, TN 37208.

A number of studies have noted high infant mortality in the African-American population in the United States.[1-22] Infant mortality is inversely associated with socioeconomic status in both black and white populations[1-7]: the higher the social class membership of the mother, the lower the infant mortality rate.[7] The larger proportion of African Americans living in poverty is usually advanced to account for the excess infant mortality in the black population. Other factors frequently used to explain the high infant mortality relationship, in addition to lower income, are poor nutrition and less prenatal care obtained by low socioeconomic status mothers together with their frequent younger age and higher parity.[8-10]

Low birthweight is the most important correlate of infant mortality,[23,24] and so infant birthweight is viewed as an indicator of risk for infant mortality. As an indicator, low birthweight has been examined in relationship to term pregnancy[11,23] and to the extent of prenatal care received.[25] Analysis of US natality statistics using a bivariate (birthweight-gestational age) approach suggests that recent reductions in infant mortality are attributable to reduction in term low birthweight infants (<2500 g; >37 weeks), which could be the result of more effective antenatal care. The reduction of preterm low birthweight incidence (<2500 g; <37 weeks) has been less dramatic for all parturients and even less pronounced for African-American women. Such findings lead others to conclude that preterm birth rather than low birthweight is the primary cause of infant mortality in the US.[26-28]

A significant cause of infant death has been infection; this too has been related to poverty.[29,30] However, recent trends in postneonatal infant mortality (death between the ages of 4 weeks and 1 year) have indicated that mortality due to infection is decreasing.[16] This

decrease does not change the ratio of black-to-white infant deaths, suggesting that the higher infant mortality rate among African Americans is not due to higher infection rates. Investigators frequently attribute post-neonatal infant mortality more to social and environmental conditions rather than to low birthweight.

In an extensive analysis of perinatal mortality, Naeye attempted to correlate data for a variety of socioeconomic factors but found that a residual black-white difference persisted and appeared related to a higher infection rate in blacks. Such differences tend to promote speculation about biological differences connected with race despite the fact that risk tends to decrease with improved socioeconomic status condition.[8] Variables such as education, income, professional attainment of the household head, maternal age, parity, influencing nonobstetrical conditions, spousal eligibility for socioeconomic status cohort membership, and extent of prenatal care utilization are some factors compared in longitudinal black-white groups. Also, personal maternal behavioral variables, such as smoking, alcohol usage, exercise, and employment, that could influence birthweight have been considered.

Risk factors inherent to a group clearly affect perinatal outcome; several recent studies have been conducted to determine the extent that the elevated risk for low birthweight or preterm births in black mothers would persist after controlling for biological, behavioral and socioeconomic status factors.[1,12,13,26] Only one of these studies tends to show that increased risk factors account for essentially all of the poorer outcomes in African Americans.[26]

Two factors characterize these studies: they are ecological or cross-sectional in nature, and they all find excess infant mortality in the black population. Cross-sectional and ecological studies may attempt to equate black and white infant mortality by similar socioeconomic status rankings, but most studies are plagued by the relatively small numbers of blacks in middle and upper class positions. More importantly, these studies do not account for the length of time in social position. It can be argued that a "newly arrived" black middle class family would not necessarily have the same education, life-style, or class stability as a "third generation" middle class black or white family. Thus, there is a need for an African-American study population characterized by sustained high socioeconomic status, which would provide birth outcome data for comparison to a similar white group.

Cross-sectional and ecological studies do not provide the opportunity for exploration of any intergenerational effect on birth outcomes. If there is a racial intergenerational effect (such as low birthweight), previous studies have been inadequate. Those few studies that have examined perinatal outcome across generations have either excluded blacks or were conducted outside the United States.[31-33] Furthermore, the need to study intergenerational perinatal outcome effects in the American population has been recognized.[34] Given the cross-sectional nature of previous study populations, what seems needed to better answer questions is a longitudinal study of a black population characterized by sustained high socioeconomic status.

METHODS AND STUDY GROUP

To answer some of these questions, we are examining health data from blacks and whites of relatively high sustained socioeconomic status for second- and third-generation outcomes. The Meharry Cohort Study forms the foundation of our patient base. Four hundred seventy-two African-American former medical students matriculating at Meharry Medical College entered a longitudinal study between 1958 and 1965 to investigate the natural history of hypertension and atherosclerosis. An additional 235 former Meharry students (200 medical students and 35 dental students) have been included to increase the statistical power of the study analysis. Birth certificates, hospital records, and a questionnaire are being used to obtain reproductive data on the participants. The primary dependent variable is birthweight, but other perinatal outcome dependent variables are considered. Independent variables consist of factors relating to education, income, social status, and nonobstetric health entities.

The Meharry Cohort Study was begun in the late 1950s by John Thomas, MD, a cardiologist at Meharry Medical College, to obtain sociodemographic information and to make baseline cardiovascular assessments in blacks.[35,36] This group consisted of 519 third- and fourth-year Meharry medical students. Of these medical students, 472 volunteered to be a part of this study; 37 students were found to be hypertensive at the time and were not included although they remain accessible to our study. As stated earlier, the additional study group is comprised of 235 former medical and dental students from 1966, 1967, and 1968. Thus, our total cohort consists of 707 first-generation members.

The most persistent demographic feature shared by the former Meharry students is their educational attainment. All had at least 15 years education and virtually all had earned college degrees prior to their admission to Meharry. All graduated from medical/

dental school and became medically and economically successful practitioners of medicine or dentistry.

Continuous mail contact has been maintained with the Meharry cohort, and the group has been examined and compared with a similar white cohort at Johns Hopkins University School of Medicine (the Precursor Study). The two institutions have collaborated in comparing the two cohorts for the risk of hypertension.[37] However, for our study, we are indebted to Michael Bracken, PhD, of Yale University, who has arranged to share data from his cohort of 4000+ females for comparison with our group. His cohort is comprised of 80% white patients and 20% nonwhite patients. This study was conducted during the 1980s and parallels births to our second-generation cohort.[38] His data collection process also parallels ours and includes the following parameters: education, gestational age, perinatal outcome factors, race, socioeconomic status of head of household, and source of maternity care.

Any study involving the interrelatedness of perinatal and other health-care outcomes to socioeconomic status are extremely complex by their nature. Given this situation, we recognize that the success of the project can be no better than the quality of its data collection tool (questionnaire). It became crucial therefore to define precisely what the data tool should seek to answer and what form it should take. To accomplish this goal, a National Advisory Committee was formed, and a professional data collection group, Survey Research Associates Inc (SRA), was retained. Through mutual input, a questionnaire was devised consisting of demographics, pregnancy history, reproductive information, labor and delivery experience, and life-style.[39,40]

Information gathered from medical records and birth certificates was used as an additional source of patient information. For those failing to respond to initial data collection efforts, telephone interviews were conducted, and on-site interviews were arranged in participants' home cities as needed. The Meharry cohort has an established track record for its ability to retrieve data from its participants. Their annual response rate ranges between 85% and 90%.[41-43]

The data collection steps used in this study are summarized in the Figure. These eight data collection steps provide a "walk through" of the procedures involved and also takes into account the attrition that inevitably accompanies research of this type.

The sample size was tested to determine if the number of subjects in the study population is large enough to fulfill the specific aims of the proposal. Originally, the number of first-generation Meharry subjects in this study was approximately 500; if we reach 450 of these and assume that two offspring is the total fertility rate of this group, we expect 900 offspring to comprise the second generation. Most of these would not have yet passed through all of their childbearing years. Thus, we assume 1.5 to be the average number of children born to the second-generation members. This would result in a total expected number of 1350 subjects comprising the third generation of the Meharry cohort. However, as our study progressed, it became apparent that childbearing in the second generation of the cohort was not occurring as early as we had speculated. Hence, to help assure a total of 1350 third-generation offspring (grandchildren of the original cohort) and to satisfy statistical power, we enrolled the additional 235 medical and dental students who matriculated at Meharry for the years 1966 to 1968.

DATA ANALYSIS

This study attempts to answer the following question: Given the same educational background, psychosocial status, economic, and nonobstetrical factors, would the mean birthweight for black newborns be the same as that for whites?

Two major approaches are being used to analyze the data. In the first approach, the dependent variable is continuous and is distributed normally or approximately so; therefore, analysis of covariance (ANOVA) will be used to analyze these data.[44] This method will allow blacks and whites to be compared with respect to the corresponding perinatal outcome, ie birthweight, after adjusting for the presence of other factors.

The second approach is being used for noncontinuous dependent variables. This approach is being used when birthweight is dichotomized into two categories (low birthweight versus normal birthweight). The analysis will be done using contingency table methods. From these tables, adjusted odds ratios will be determined, and tests of their significance will be obtained using the Mantel-Haenszel chi-square statistic.[45]

PRELIMINARY FINDINGS

Data have been collected and analyzed for the first 189 former Meharry students (first generation); they reported 494 births. Of these 494 births, 57 (11.5%) were low birthweight infants and four (0.81%) were very low birthweight infants.

For white patients during this time period (1955 to 1965), the low birthweight rate was 7.2%; for nonwhite parturients, the low birthweight rate was 13.8%. During the same time period, the very low birthweight rate for

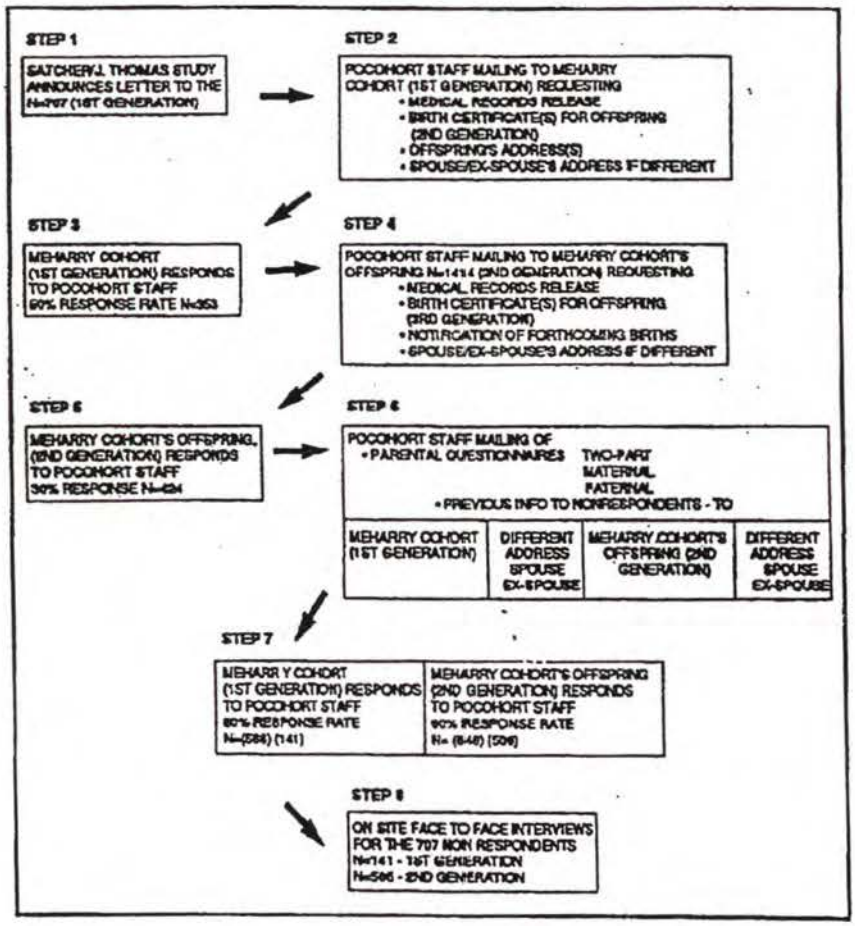


Figure. Chart outlining data collection steps to determine perinatal outcome in the Meharry cohort.

white parturients was 0.99% and 2.31% for nonwhites. The combined very low birthweight rate for both races was 1.16%.[46]

Births to the second generation (children of the Meharry cohort population) number 108 births (grandchildren of the original Meharry cohort). Of these, nine (8.3%) low birthweight infants were reported. There were no very low birthweight infants reported among these 108 births. National data collected in 1989 revealed a 5.7% low birthweight rate for white parturients, 13.2% for black parturients, and 6.2% for other nonblack parturients (Hispanic and Native American) during that same period.[47]

When final data analysis is conducted, whites and other nonblack parturients will be matched with blacks for equivalent socioeconomic status.

We anticipate concluding the present study in 18 months, depending on how supportive our Meharry graduates are in responding to us. At that time, we hope to substantiate our hypothesis that there is no significant difference in birthweight distribution among infants born to parents of the same socioeconomic status with the same risk factors irrespective of race.

Acknowledgments

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Teaching Obstetrics and Gynecology in a Managed Care Environment



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> *"With important changes ahead, forcing our profession to dive into a managed care system, we must prepare for and take advantage of opportunities for learning the new system before it is here."*

The health care environment fluctuates these days almost as often as do the creators of the Health Security Act. What is the possible impact of the administration's directive to make health care the most cost-effective scheme possible? I believe it is the thrust toward managed care which compells us to ask how this might affect medical education--particularly undergraduate medical education in obstetrics and gynecology.

By the year 1998, when the Health Security Act is to be fully instituted, most of the U.S. population will be covered by HMO's or some other composition of managed health care through regional health purchasing cooperatives or "alliances." It seems that most healthy women will eventually get their health care services at less costly HMO's rather than through their private or faculty practitioners. It is possible that managed health care could increase patient accessibility at teaching hospitals, especially in areas where obstetricians, gynecologists and allied health professionals collaborate and establish group practice settings. These programs must include ingredients of managed care that will entice patients. The reimbursement for these services must be sufficient to support our educational change. If this funding is not sufficient, then alternative sources must be identified.

According to revisions of the American Health Security Act of 1993, ob/gyn physicians have been declared primary care providers. Specifically, obstetrics and gynecology is now included as a primary care specialty for GME reimbursement. Therefore, with health care reform comes some sort of security knowing there is inclusion. But to stay above water, we will need to encompass primary care into our education programs. Quality and cost-effective services are truly the hallmarks of health care for now and in the future. However, once again, reimbursement to health science centers must be sufficient to support our educational purposes.

Generally speaking, in the aggregate, managed care patients should be paying less out-of-pocket expenses than they are now. This is due, in large part, to less emergency room service and unnecessary inpatient, outpatient and laboratory services. In time, quality of care, including preventive care, should ease the rising cost of emergency treatment. Continuity of care, as well as the security of knowing patients have coverage, are added benefits of the new system. But, all of these incentives can only work if patients stay in these managed care programs; otherwise, preventive care cannot be tracked. I should add that the benefits from preventive care are not absolutely immediate. Physicians are also presented incentives in managed care programs through a capitation payment system that allows incentive payments when capitation funds are not utilized.

The skeptics are concerned that some managed care programs may over-regulate utilization of services in order to cut costs resulting in limited services. The potential for this seems greater in rural areas. There are restraining properties in some plans that make it essential to break the provider-patient relationship. The health care design that seems to make the most sense would be a combination of managed care and the traditional fee-for-service or indemnity care, which would free patients to go outside the plan and seek specialty services elsewhere. In fact, in the United Kingdom each year, 25% of subscribers to the government-sponsored health care system go outside of that system to utilize private sector care.

The idea of collaborative practices--specifically, working with allied health professionals to secure patients who need a variety of care, is the wave of the health care future. Women's health care centers are prevalent in many urban areas. Since family practitioners or nurse midwives can provide annual pap smears, pelvic exams, contraceptive counseling and prenatal care, obstetricians/gynecologists who are interested in continuing to practice are forced to practice primary care at lower costs.

From my reading, I find that "physician-management" companies are the current trend toward installing managed care systems across the country. They have been around since the 1980s, but have become much more popular in the past three years. These companies, such as American Health Care Group, First Physician Care and PhyCor, to name a few, "buy up" primary care physicians. This, in turn, expedites the need for more primary care physicians. Large companies, and local and federal government, already rely on managed care programs to cut costs. Analysts agree that this system will not be limited to these areas but, rather, will become universal.

Physicians who join "physician-management" companies will benefit in a number of ways: up-front fees, long-term

Continued on page 8

Teaching Obstetrics and Gynecology (Cont. from page 7)

contracts, medical liability insurance coverage, job security in an uncertain health care future, and administrative responsibilities and overhead costs handled by others. However, they will also be faced with having a corporate employer to whom they must report, an overseer that accounts for the quality of health care they provide, and individual cost controls. The physician will not have the freedom that he or she had in the past.

Yet another consideration is what effect, if any, the entry of more female physicians into the health care provider pool will have in the managed arena. Hopefully, managed care will not result in assembly line visits causing compromised care.

What does all this mean to the medical educator? Some of these issues will be addressed at our next two meetings. At the 11th Annual Faculty Development Seminar in Maui, Hawaii, January 9-12, 1994, we will have the opportunity to hear Doctor Warren Pearse's plenary session on "Faculty Members and Future Projections for Ob/Gyn Departments: Who Will Teach the Medical Students?" as well as Doctor Martin Stone's presentation on "Obstetrics and Gynecology: A Discipline in Transition" and Doctor Ralph Hale's session on "Primary Care in an Ob/Gyn Clerkship."

In March, at the CREOG and APGO Annual Meeting in Nashville, Tennessee, primary care is the predominant topic as you can discern from the preliminary program on pages 2-5 in this newsletter. Thursday afternoon is busy, beginning with Doctor Marilyn Gaston's general session on primary care issues, followed by Doctor Leo Duran's session on "What is Primary Care?"

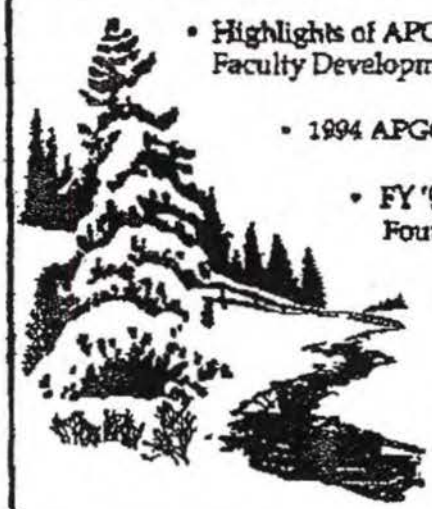
Doctor Harry Jonas will speak on "Ensuring a Role for the Ob/Gyn in Primary Care" and Doctor Roger Turnell will share his impressions of "Primary Care in Canada." Issues concerning health care and curriculum reform will be included in breakout sessions.

Earlier this year, I had the opportunity to present comments to the Presidential Health Care Task Force chaired by Mr. Ira Magaziner, Senior Advisor to the President for Policy Development. In my presentation, I commended the Clinton administration for its commitment to primary health care and its efforts to support education of primary care practitioners. And, so as to not lose ground, I strongly urged that it is essential for the Administration to maintain funding for the disproportio share of hospitals structure or provid other mechanisms that will assume th continuation of this critical funding source. This consideration is essential given that the Medicaid Program is b revised in the Health Security Act. Support for hospitals that serve large numbers of medically indigent or nea indigent patients must be subsidized.

With important changes ahead, fo our profession to dive into a manage care system, we must prepare for and take advantage of opportunities for learning the new system before it is b To the extent that we can, we must become proactive. Our responsibiliti threefold: 1) we must recognize that are primary care physicians; 2) we m accept a managed care system as the direction of the future; and 3) we mu position our academic curriculum to reflect these changes. It will not take overnight; therefore, we can do some strategic planning now to facilitate t transformations. Join us in Maui and Nashville to acquire some new guid and to share your experiences with

Looking Ahead...

The Quarterly Report, Winter 1994



- Highlights of APGO/Syntex Faculty Development Seminar
- 1994 APGO Membership Directory
- FY '93 APGO Medical Education Foundation Annual Report
- Announcement of Parke-Davis Scholars
- The Process of Promotion and Tenure—*A Dean's Perspective*

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Ambulatory Gynecologic Surgery

WHY AMBULATORY SURGERY?

The rapid rise in the cost of health care in this country is of great concern. In the fiscal year 1974–1975 we spent 118.5 billion dollars for health, or 8.3% of our gross national product (GNP). Health costs for 1978 are estimated at 180 billion dollars. In this decade, the percentage of our GNP devoted to health has risen by over 40%. If such a rate increase were to go unchecked, health expenditures would exceed 20% of our GNP by the end of this century. Hence if the premise is accepted that health care costs are too high and their rate of increase is too rapid, ambulatory surgery becomes one of several important mechanisms which promise cost containment.

The magnitude of such savings should be quite substantial when one considers the numerous gynecological surgical operations done as inpatient hospital procedures (e.g., D & C, laparoscopy, sterilization) which usually could be performed safely, efficiently, and conveniently on an ambulatory basis. Moreover, other surgical disciplines also have the capacity to shift a portion of their inpatient surgery to the ambulatory setting. Data published in 1971 by the National Center for Health Statistics reported 15,774,000 operations performed as inpatient hospital based procedures. Imagine the reduction in cost of health care system which could accrue by shifting 20% of these procedures to the ambulatory setting. Although no total dollar amount can be quoted, reduction in the charges for some ambulatory procedures as compared to inpatient charges have resulted in savings of as much as two-thirds. Given the

volume of surgery done in this country, an overall reduction in charges of just one-third would be substantial.

In addition to cost containment for the health care system, ambulatory surgery can decrease direct costs to patients. This is particularly true for patients not covered by third party insurance or covered by policies which provide only partial coverage with the patient defraying the difference. Beyond this, surgical procedures done on an ambulatory basis cause the loss of less time from jobs, thereby strengthening patients' economic positions. Ambulatory surgery offers psychological as well as economic benefits to patients. For many patients it is more convenient to recover at home in familiar surroundings with family members in attendance. The hospital environment can cause significant anxiety for patients; this is particularly true in children and adolescents.

The operating surgeon, too, is beginning to recognize the efficiency and indeed the economic advantage of ambulatory surgery. Ambulatory surgery reduces time spent with inpatient follow-up visits and associated hospital administrative paperwork. Also, the accuracy of the ambulatory surgical schedule is much more certain than the hospital surgical schedule, where long and complicated cases are frequently disruptive. The elimination of such uncertainties makes way for much more efficient use of the busy surgeon's time.

The ultimate justification for ambulatory surgery, however, is its effectiveness and safety. A report of 14,000 outpatient surgical procedures conducted at the George Washington University Hospital from March 1966 through December 1971 revealed no deaths. The surgicenter in Phoenix, Ariz. reported more than 5000 outpatient operations in a 20 month period with no deaths and but a single complication that necessitated patient hospitalization.

Hence the factors of economy, convenience, and safety encourage the trend toward ambulatory surgery.

BARRIERS TO IMPLEMENTATION

In spite of reasons for increasing the use of ambulatory surgery, there is nonetheless no great rush in that direction. What barriers inhibit the spread of ambulatory surgery? Some stem simply from the mechanics of setting up an ambulatory surgical service and will be considered later. On the other hand, many barriers result from apathy and from the disincentives for cost containment in our current health care delivery system.

The apathy is related in part to the kinetics of effecting change.

Change requires an energy output—a movement from that which is known and usually comfortable to that which is unknown and possibly uncomfortable. With no clear stimulus or reward for change—with, in fact, negative incentives for change—the status quo remains unaltered. Only very recently and at a very limited level has there been any stimulus for ambulatory surgery.

But beyond this inertia, there has been an active resistance to the expansion of ambulatory surgery. This resistance is created by a financial reimbursement system which promotes hospitalization of patients who might otherwise be cared for in the ambulatory setting. Many insurance companies, for example, refuse to reimburse at all for operations done in the ambulatory setting; others reimburse at lower rates. In the past, federally supported programs such as Medicare, Medicaid, and CHAMPUS have followed this general pattern of reimbursement. Fortunately, this pattern has begun to change.

Another factor that has affected the development of ambulatory surgery is professional liability insurance. Understandably, insurance companies have shown reluctance to provide coverage when certain expensive safety equipment is not available. Often, particularly in the solo practitioner's office, such equipment was prohibitively expensive; however, as group practices, surgicenters, and hospital based ambulatory surgical units developed, insurers have become more willing to extend liability coverage for surgery performed in an ambulatory setting.

There exist other barriers which are only indirectly financially related. Hospital administrators often pressure surgeons to "utilize" hospital beds. Such a practice, of course, increases occupancy rates and subsequently hospital income. Further, it helps amortize expensive hospital programs and equipment, some of which have been installed at the behest of operating surgeons.

In many areas, hospitals are physician owned and operated and hence subsidized by them. There is clearly little or no incentive for such physicians to utilize ambulatory facilities.

The issues of peer review and anesthetic risk have been raised as possible barriers to ambulatory surgery; however, neither issue now appears to be valid. Peer review has been accepted as a means of helping assure quality control; accordingly, appropriate peer review mechanisms must be required of all ambulatory surgical units.

Anesthetic complications occur irrespective of the locale of the surgery; however, data indicate that although these complications are possible and require careful patient selection, they do not render outpatient anesthesia unacceptable.

In all these examples of barriers to ambulatory surgery, it can be

seen that our present health care system survives on illness rather than wellness. The powerful financial incentives and rewards encourage inpatient hospitalization.

PLANNING AMBULATORY SURGICAL SERVICES

ACOG Position

The initial step in planning ambulatory gynecologic surgery ought to be a review of *ACOG's Standards for Obstetric-Gynecologic Services*. This manual statement contains a special reference to outpatient procedures. At the onset, the document categorizes the nature and magnitude of ambulatory surgery to be conducted; the extent of surgery and the anesthesia requirement dictate the nature of the physical setting, regulatory requirement, personnel, and equipment.

ACOG's standards define two categories of procedures. Category I covers surgical procedures that require general or regional block anesthesia or any surgical procedure which entails a significant degree of risk irrespective of anesthetic requirement. Category I includes laparoscopy, culdoscopy, dilatation and curettage, second trimester pregnancy terminations by any means, examination under anesthesia, and extensive fulguration of vulva lesions.

Category II procedures are those which require local infiltration anesthesia or none at all and have been done historically in the gynecologist's office. These procedures are deemed to be low risk, e.g., cervical punch biopsy, cervical cauterization, culdocentesis, etc.

ACOG recommends that category I procedures be conducted only in facilities possessing full surgical anesthesia and resuscitation capability. Additionally, the facility should be sanctioned by license or accreditation as required by state and local laws. Further, the surgical and anesthesia personnel should be indistinguishable from those available to the hospitalized patient. All non-hospital-based ambulatory surgical units should have an existing transfer agreement with an accessible hospital to accept emergency cases. The subsequent discussion of ambulatory surgery in this chapter will primarily apply to category I procedures as defined by ACOG in its Standards.

Health Planning Requirements

In order to initiate category I ambulatory surgical services, basic health regulatory requirements must be satisfied. Local health planning agencies created by the National Health Planning and Resources Devel-

opment Act of 1974 (PL-93-641) provide for this mechanism. The initial request is made locally through the Health Systems Agency (HSA). From there the HSA makes its recommendations to the State Health Planning and Development authority (SHPDA). A favorable recommendation by SHPDA satisfies the certificate of need requirement, a requirement which must be met by both publicly and privately funded proposed expansion programs. From this point on, regulatory requirements vary in different states and hence must be investigated locally; however, there are some basic principles which have general applicability.

There needs to be some mechanism to assure quality. Some form of medical audit must be established to periodically review medical and surgical procedures conducted in the facilities. The medical audit body must be empowered to enforce standards. Although Professional Standards Review Organizations (PSRO) review of ambulatory services is not required by law, some feel that PRSOs will utlimately evolve as the major instrument for setting standards for ambulatory surgical facilities.

Any physician utilizing an ambulatory surgical facility should be required to be a member in good standing in a locally accredited hospital. This is a requirement by law in the State of Tennessee.

An ambulatory facility should establish a mutually agreed upon transfer arrangement with an acceptable acute surgical care hospital to handle potential emergencies. Reasonably close proximity must be a prime consideration. The hospital based ambulatory surgery unit, however, has obviated this problem.

Other planning requirements relate to liability insurance protection and third party insurance payments. Obtaining adequate liability insurance protection is contingent primarily upon having a secure legal status, i.e., a licensed center, qualified personnel, and a well planned mechanism for referring complications.

As pointed out earlier, for many years third party insurance carriers refused or were reluctant to reimburse for outpatient surgery. This trend is now beginning to change, stimulated in great part by the need for cost containment. Accordingly, a favorable licensing status and adequate liability protection should essentially assure third party reimbursement of reasonable charges for ambulatory surgery.

Physical Facilities

There exists significant latitude with respect to the physical characteristics of the ambulatory surgical site; however, Martin recognizes four general settings, characterized as follows: (1) the office setting, (2) the group or clinic setting, (3) the freestanding surgicenter, and (4) the

hospital based surgical facility—thought by some to be the most ideal setting for the ambulatory surgical unit.

Little if any modification is necessary for the examination rooms in the offices of most gynecologists when only category II procedures are carried out. These are low risk procedures utilizing only local anesthesia or none at all. In order to provide the more sophisticated category I procedures, however, anesthesia personnel, operating and recovery room personnel, full monitoring and resuscitation equipment, and emergency electrical power must be supplied, and state and local building codes must be met.

In facilities where surgery is performed utilizing general anesthesia, it is likely that a so-called class III-C building will be required. Basically, this is a fireproof structure; however, to reduce construction and renovation costs, waivers in the fire code can be obtained by excluding the use of flammable anesthetic agents. This eliminates the need to install costly conductive flooring and explosive-proof switches and receptacles. Such an arrangement also allows for the use of any type of electrical equipment within the operative suites; moreover, all types of static producing synthetic materials can be worn by operating room personnel.

Designing an ambulatory surgical facility obviously requires careful planning. The unit must be prepared to provide for a wide range of services, which in addition to surgery may include the care for nonsurgical gynecologic patients. Aside from the patients themselves, there will be family members, men, women, and children, and a variety of permanent and transient personnel. The physical design must allow for the presence of female patients who are but slightly clad; hence there has to be adequate physical separation, but not to the extent as to impede the smooth flow of activities.

One cannot define the optimal design for an ambulatory surgical unit; this will depend primarily upon the size of the surgical group and the anticipated volume and variety of gynecologic surgery to be conducted. It appears that approximately 2200–2500 ft^2 (200–230 m^2) total floor space per operating room is required to support a four operating room, freestanding, multidisciplinary center. It appears this area per operating room could be reduced in a larger unit or possibly in one restricting its surgery exclusively to gynecologic procedures.

The 20 ft × 20 ft (6½ m × 6½ m) operating room works well. The other space must support a core area of anesthesia, control station, sterile storage, scrub area, cleanup area, waiting room, recovery room, lounge and locker areas, maintenance areas, and corridor space. Also, parking space for both patients and staff must be taken into consideration, as well as an approved area for waste disposal.

Equipment

The equipment required to perform category I ambulatory surgery must be as complete as that utilized in the accredited hospital operating room. This equipment can conveniently be divided into anesthesia equipment and surgical equipment. Each operating room requires the following anesthesia equipment: (1) anesthesia machine equiped with CO_2 absorber, (2) cardiac defibrillator, (3) oscilloscope, (4) fixed and portable suction units, (5) laryngoscope and various blades, (6) endotracheal tubes, (7) portable respirator, and (8) airways.

In addition to this basic anesthesia equipment required for each operating room, the surgical unit should have at least one "crash cart" (for cardiopulmonary resuscitation) containing such items as intravenous fluids, syringes, sterile gloves, sutures, cutdown tray, tracheostomy tray, cardiac arrest board, and polyethylene tubing. Some of the drugs essential to such a cart are calcium gluconate, deslanoside, dextrose, diazepam, diphenhydramamine, epinephrine, glucagon, isoproterenol, lidocaine, naloxone, sodium bicarbonate, methyl prednisone, atropine, calcium chloride, pronestyl, phenytoin sodium, propanolol, pitocin, ergotrate, and anectine.

Surgical equipment required can be subdivided into surgical instruments and operating room support equipment. This latter group would include fixed and portable operating room lights and an operating table capable of being mechanically or manually raised, lowered, tilted, and rotated. Comfortable leg stirrups (preferably the heel ankle support type) must be available.

Other supporting equipment would include an instrument sterilizer, electrocautery-coagulation machine, and storage cabinets; for convenience, disposable gowns and drapes are recommended.

The extent and complexity of surgical instruments required for ambulatory gynecologic surgery will be determined by the type of surgical procedures to be done. Procedures can be automatically classified as those involving the vulva, vagina, cervix, endometrium, fallopian tubes and ovaries, and peritoneum. Five basic surgical trays should address all the gynecologic surgical needs of the ambulatory unit. We recommend that we call the child tray for our vulva ambulatory surgery (Table 21–1). The instruments for vaginal, cervical and endometrial surgery are listed in Table 21–2, and when necessary the child tray instruments are also used. The laparoscopy tray is used for diagnostic and therapeutic tubal, ovarian, uterine, and peritoneal conditions (Table 21–3). The instruments utilized in our minilap tubal sterilization tray are described in Table 21–4, and the instruments required for our standby laparotomy pack are described in Table 21–5.

Table 21-1
Child Tray

6 curved mosquitoes	2 Metzenbaum scissors
14 curved hemostats	2 knife handles (no. 3)
3 Crile hemostats	2 Senn retractors
6 straight hemostats	2 army/navy retractors
6 Allis clamps	1 muscle retractor
4 straight Ochsner	1 probe
8 towel clips	1 grooved director
2 sponge sticks	2 tissue forceps
2 needle holders (6 inch)	2 thumb forceps
2 medicine cups	1 Adson with teeth
1 suture scissor	1 Adson without teeth
1 curved Mayo scissors	

It is recognized that most experienced surgeons have a preference as to surgical instruments, and, of course, competent work can be accomplished with a variety of equipment. Most surgeons, however, will find quite satisfactory the instruments utilized on the five trays which have just been described.

Personnel

Procuring personnel for outpatient surgical facilities has been relatively simple for several reasons. The vast majority of outpatient surgical facilities function only during hours of the usual working day and are

Table 21-2
D & C Pack

1 knife handle	1 Goodel dilator
1 Graves speculum	8 Hegar dilators
1 weighted speculum	3 dull curettes
3 towel clips	4 sharp curettes
2 ring forceps	1 needle holder
1 biopsy forceps	2 medicine cups
1 radium grasping forceps	1 knife handle (no. 7)
1 uterine dressing forceps	suction machine
2 Jackson retractors	8, 10, and 12 mm curved plastic
2 Sims retractors	cannulas
2 double tooth tenaculums	1 biopsy forceps
1 uterine sound	3 single tooth tenaculums

Table 21-3
Laparoscopy Instruments

Cohen-Eder cannula	Grasping forceps
Small acorn	Silastic hose for CO_2
Large acorn	Fiberoptic light cable
Small conical trochar with sleeve	Insufflator unit
Large conical trochar with sleeve	Foot switch
Verres needle	Connecting cable
Biopsy forceps—1 pair	Ground plate
Hook scissors—1 pair	Aspirating needle
Tactile probe with cm markings	Suction cannula
Laparoscope	Modified Rolmar grasping and cutting forceps

closed nights, weekends, and on holidays. It is not difficult to appreciate the attractiveness of this concept to prospective employees.

It also appears that the reduced physical demands of shorter surgical procedures are attractive to personnel. Unlike a large inpatient hospital operating room staff, the number of personnel in the average ambulatory surgical unit is small, and usually this creates a sense of camaraderie resulting in a positive working environment.

Ideally, there should be two registered nurses for each operating room; however, in a unit with four operating rooms, for example, a certain volume of the surgery can be expected to be done under local or regional block anesthesia. Hence the nursing training requirements might be less, thus enabling licensed practical nurses to be used. Also, in some instances operating surgeons will provide their own surgical nurses. Minimally, 1.5 registered nurse full-time equivalents are needed for each

Table 21-4
Minilap Tray

Openside speculum	1 tissue forceps with teeth
Hulka tenaculum	1 Mayo Hegar needle holder 7 inch
2 sponge forceps, 8 inch, straight	4 Kelly Murphy straight 5½ inch
Metal medicine cup	2 Rochester-Pean (light) curved 6½ inch
13/15 and 17/19 catheter tray	1 Rochester-Ochsner straight
Sterile Foley catheter tray (closed drainage system)	1 Mayo dissecting scissors straight 5½ inch
2 army retractors	1 Mayo dissecting scissors curved 5½ inch
2 Richardson retractors	2 Babcock forceps 5½ inch
1 Dressing forceps 6 inch	
2 Sponge forceps 8 inch	

Table 21-5
Standby Lap Tray

1 Mayo scissors straight 5½ inch	1 Metzenbaum scissors curved 7 inch
1 Mayo scissors curved 5½ inch	1 Army retractor (set of two)
12 Halsted mosquito hemostat straight 5 inch	2 Kelly Retractor 2½ × 2 inch blade
12 Kelly curved 5½ inch	2 Kelly retractor 2 × 1½ inch blade
6 Kelly straight 5½ inch	2 Richardson retractor 2 × ¾ inch blade
6 Rochester-Ochsner forceps straight 6¼ inch	8 sponge forceps 9½ inch
6 Allis tissue 4 × 5 teeth 5½ inch	4 Babcock forceps 5½ inch
2 Mixter forceps curved 7¼ inch	4 Rochester-Pean forceps, heavy model, 6¾ inch
1 Dressing forceps 6 inch	1 Rochester-Ochsner forceps, curved, 7¼ inch
1 Tissue forceps 1 × 2 teeth 6 inch	1 Martin thumb tissue forceps 6 inch
2 Crile-Murray needle holder 7 inch	1 O'Sullivan-O'Connor retractor

operating room in an ambulatory facility. Their function includes coverage of the pre- and postanesthesia rooms.

An orderly and an instrument room technician complete the nonanesthesia nursing staff. A four operating room surgical unit can usually be supported quite well by two orderlies and one instrument room technician.

At least one anesthesiologist should remain in the unit until all surgical patients have been fully recovered from their anesthesia. With the onsite supervision of an anesthesiologist, nurse anesthetists can be utilized commensurate with their training, skills, and existing laws.

DELIVERY OF AMBULATORY SERVICES

Anesthesia

As mentioned earlier, until recently most liability insurance companies refused or were reluctant to provide coverage for outpatient surgery. In all fairness to them, however, their reservations were probably justified until recently. With soaring adverse malpractice judgments and no standards of care established, insurance companies particularly feared cardiovascular emergencies associated with outpatient anesthesia; however, as standards requiring sophisticated full resuscitation equipment in ambulatory facilities performing category I surgery have begun to emerge, the resistance has begun to lessen. In addition to equipment and qualified personnel, the factors of patient risk status and type and extent of anesthetic agents used are major factors influencing safety.

Patient Selection

Obviously, great caution must be exhibited in the selection of patients for ambulatory surgery. The American Society of Anesthelogists (ASA) has devised a classification system which is a most useful guide for patient selection (Table 21–6). The extent of postoperative morbidity and mortality correlate with the classification number. It would appear that according to the ASA classification, patients selected for category I ambulatory surgery should be restricted to classes I and II. Additionally, the extent of the proposed surgery must also be an influencing factor. Patients in class II with mild systemic disease, for example, might not be suitable candidates for outpatient ambulatory surgical sterilization procedures.

There are other patient selection considerations. Some class I and II patients are not suitable for outpatient surgery. This group would include the senile, patients of significantly reduced intelligence, patients with personality disorders, drug addicts, and alcoholics. Also, logistical problems such as unavailability of transportation or the absence of a chaperon will exclude some ASA class I and II patients from ambulatory surgery.

There are some special counseling considerations for abortion and sterilization patients which will exclude them as candidates for ambulatory procedures although they may meet ASA's class I and II standards. These special counseling considerations for abortions and sterilization patients will be addressed in this chapter's section on surgical fertility control procedures.

When selecting patients for outpatient surgery, a careful history must be taken, particularly with respect to the patient's anesthetic history. Any previous complications or allergies must be taken into full account. Careful review of current or recent past drug intake must be noted in order to avoid drug interactions with anesthetic agents.

Required laboratory tests will vary somewhat depending upon the

Table 21-6
American Society of Anesthesiologists Classification

Class I	A normally healthy patient for an elective operation
Class II	A patient with a mild systemic disease
Class III	A patient with a severe systemic disease that limits activity but is not incapacitating
Class IV	A patient with an incapacitating systemic disease that is a constant threat to life

type of procedure, the patient's age, and the patient's classification status; however, irrespective of these variables, the hemoglobin, hematocrit, and urinalysis are obligatory. Complete blood chemistries, chest x-ray, electrocardiogram, and other tests must be utilized as deemed appropriate based on the clinical judgment of the operator.

The format for recording these data and documenting pre- and postanesthetic notes should comply with the same Joint Commission on the Accreditation of Hospitals (JCAH) standards utilized for hospitalized surgical patients.

Liberal use should be made of printed patient instructions both before and after surgical procedures.

Anesthetic Choice

Anesthesia selected for ambulatory surgical patients must allow for the patient to recover and return home within approximately 8 hours from the time of admission. This key requirement reduces considerably the anesthetic techniques available for ambulatory surgery as compared to the hospitalized surgical patient.

Neither spinal or epidural anesthesia is well suited for short stay surgery. In addition to the unpredictable recovery time, there is a possibility of troublesome postspinal headaches. The development of acute urinary retention is also a problem which cannot be readily addressed by the patient in her home setting.

In order to hasten recovery time, anesthetic preoperative medication, if used at all, should be kept to a minimum. A frequently used technique is to administer intravenously 0.4 mg atropine and 250 mg of a 2% solution of pentothal sodium followed by either halothane (Fluothane) or enflurane (Ethrane) plus a nitrous oxide–oxygen mixture. The simultaneous use of nitrous oxide lowers the effective concentration of Ethrane or Fluothane, resulting in a shorter emergence time from anesthesia. Anesthetic agents that have prolonged induction and recovery times are avoided, as are those associated with a high incidence of posteroperative nausea and vomiting.

With the exception of laparoscopy, endotracheal intubation is usually avoided in ambulatory surgery. Intubation frequently requires the use of potent muscle relaxants such as succinylcholine, resulting in marked postoperative muscle pain. Sore throat and hoarseness are also annoying possibilities.

Aside from toxicity secondary to overdoses and allergic reactions, regional nerve block presents few recovery problems for the gynecologic surgeon. Lidocaine (Xylocaine) and mepivacaine (Carbocaine) are used for paracervical block. Care must be taken, of course, to avoid the intravascular administration of these drugs.

Surgical Procedures

Once patient selection and anesthetic choice have been decided, specific surgical procedures can be considered. Vulval, vaginal, cervical, and endometrial ambulatory surgical procedures will be discussed in this section. Unlike abortion and sterilization procedures, which will be discussed later, there is no special counseling to be taken into account.

Printed preoperative instructions should be provided to patients undergoing ambulatory surgery for vulval, vaginal, cervical, and endometrial lesions. The patient is instructed (1) to take nothing by mouth after midnight of the evening preceding the morning of surgery (if this instruction has not been followed, the procedures must be rescheduled), (2) to bathe and rest adequately the night before surgery, (3) not to douche or take enemas the day prior to surgery, (4) to wear casual clothing and bring no jewelry, and (5) to arrange for an escort for her return home after surgery.

On the morning of surgery prior to the administration of any medication an informed consent form is signed by the patient or, in the case of minors, by a parent or legal guardian.

VULVA

Lesions of the vulva can be managed with either local or general anesthesia, depending upon the nature of the pathology. The lesions include suspected malignancies, condylomas, papillomas, hidradenomas, hemangiomas, sebaceous cysts, fibromas, lymphomas, and Bartholin's duct cysts and abscesses. Other vulval procedures which lend themselves to outpatient surgery are hymenectomy and perineotomy.

Diagnostic biopsies should be performed using 1% or 2% lidocaine solution. In the case of suspected malignancy, the vulva should be washed with 1% acetic acid and then swabbed with 1% toluidine blue dye. One percent acetic acid is used again to remove the dye; those vulva skin areas failing to become clear of the dye are designated for biopsy. This retention of the blue dye suggests abnormal nuclear activity and hence potential malignancy.

Local anesthesia can be easily used to surgically excise small cysts and pedunculated lesions and for the performance of hymenectomy or perineotomy; however, general anesthesia is recommended for the electrosurgical removal of large condylomas and marsupialization or excision of Batholin's duct cysts.

VAGINA

The most common benign tumors of the vagina are inclusion cysts and Gartner's duct cysts. Inclusion cysts usually occur on the posterior surface of the lower end of the vagina and rarely exceed a few centimeters

in diameter. Accordingly, most often they can be removed with local infiltration anesthesia. On the other hand, Gartner's duct cysts can vary in size from a few centimeters to masses so extensive that they completely fill or even protrude past the vaginal introitus. Lesions of this magnitude are most appropriately corrected in the hospital setting with general or conduction anesthesia preceded by an adequate preoperative diagnostic workup. Moreover, these lesions can extend high in the vaginal vault, where exposure can be difficult. Hence adequate surgical assistance should be available in such situations.

There are occasionally rare benign tumors of the vagina such as fibromas, fibromyomas, adenomyomas, and endometriosis. Most of these lesions can be excisionally biopsied under local anesthesia (for the management of vaginal adenosis and adenocarcinoma see Chapter 18).

Minor traumatic lesions of the vulva and vagina can usually be managed by suturing using local anesthesia; however, extensive traumatic lesions associated with significant blood loss are best managed on an inpatient basis.

CERVIX AND ENDOMETRIUM

Outpatient surgery on the cervix is generally confined to diagnostic biopsies, excision of benign neoplastic lesions, and electrocautery and cryosurgical procedures usually for inflammatory and precancerous lesions (see Chapters 16 and 26).

Benign neoplastic lesions such as condyloma acuminata and cervical polyps easily lend themselves to ambulatory surgery. Condylomas of the cervix are relatively uncommon and when present will usually respond to the therapy provided for the associated vaginitis; however, when such cervical or vaginal lesions fail to respond or are large, excision or fulguration is preferred to podophyllin therapy. This can usually be accomplished without the use of anesthesia.

Cervical polyps are generally predunculated and may be singular or multiple. They are easily managed without anesthesia by simply twisting them free at the base with an instrument such as a ring forceps. Bleeding can be controlled by lightly applying a cautery point to the polyp base. If the polyps are multiple and the canal crowded, paracervical block as described below can be used to effect better exposure.

Cold knife conization can also be done on an ambulatory basis. Immediate hemostasis can be achieved with the Sturmdorf suture. Delayed hemorrhage, seen occasionally with this operation, usually occurs after the fifth day of surgery and can occur irrespective of where the conization procedure was originally done.

Nonlaparoscopic surgical procedures on the uterus by and large are confined to evacuation of the uterine cavity; however, this usually must

be preceded by dilatation of the cervical canal. When done under local anesthesia, this is accomplished by using 5 ml Carbocaine combined with 0.5–1 ml hyaluronidinase (Wydase) and injecting equal amounts at the five and seven o'clock positions. Five minutes should be allowed for the block to take effect. Thereafter, cervical dilatation usually can be accomplished without causing undue discomfort to the patient.

The hysteroscope is a fiberoptic instrument which is inserted into the uterine cavity through the cervical canal. This diagnostic and therapeutic tool has not yet gained wide acceptance in this country. There are, however, some notable exceptions. Sciarra and Valle reported 315 diagnostic and therapeutic procedures, 214 of which were conducted under paracervical block anesthesia. Hysteroscopy also proved useful in the diagnosis and treatment of uterine adhesions.

The laparoscope is uilized as both a diagnostic and therapeutic tool. Its use in tubal occlusion will be discussed later. Some of the diagnostic uses of laparoscopy include infertility and endocrine disorders, pelvic masses, pelvic pain, and evaluation of responses to therapy. Some of the therapeutic applications in addition to tubal occlusion are lysis of adhesions, recovery of ova, removal of foreign bodies, and uterine suspension.

The basic steps in the technique for laparoscopy include the establishment of a pneumoperitoneum; introduction of the operative trochar; and insertion of the laparoscope for visualization and use of the operative instruments for grasping, cutting, measuring, aspirating, and coagulating.

Although uterine suspension operations are generally frowned upon, there are nonetheless some occasions where they can be indicated. This can be accomplished by placing a 2 cm incision 3 cm above each inguinal ligament near its midline. A grasping forceps is used through that incision to bring the round ligments up to the anterior rectus sheath, where they are anchored with nonabsorbable suture.

SURGICAL FERTILITY CONTROL PROCEDURES

The utilization of surgical sterilization procedures has increased markedly in the past decade. It is estimated that surgical sterilization is the preferred method of contraception for couples married 10 years or more and that one-third of all married couples between the ages of 30 and 45 have chosen sterilization.

With the world's rapidly increasing population and its effect on natural resources, there have been increased efforts to develop and refine techniques which will assure fertility control. The quest has been to develop sterilization techniques with broad applicability which offer

safety, simplicity, effectiveness, and economy. The development of laparoscopic and minilaparotomy female sterilization represent steps in this direction.

The major surgical fertility control procedure is that of abortion. Elective abortion became legalized in this country in 1973 when the U.S. Supreme Court rendered its historic decision in the cases of *Rowe v. Wade* and *Doe v. Bolton*. In 1970 less than 100,000 annual legal abortions were reported. In 1978 well over one million procedures were reported.

Abortion

Legally, elective abortion can be performed in both the first and second trimesters. First trimester abortions are usually performed in an ambulatory surgical unit utilizing suction curettage. Second trimester abortions may be done using intraamniotic instillation of saline or prostaglandins, and also by dilatation and evacuation (D & E) of the uterus. It is recommended that intraamniotic infusion techniques be performed on an inpatient basis. In addition to safety, a practical reason for this recommendation is the fact that both saline and prostaglandin abortions have unpredictable latent periods, i.e., the interval between instillation of the abortifacient and the complete emptying of the uterus. Hence unless an ambulatory facility has a capacity to remain open on a 24 hour basis, these procedures are best conducted on hospitalized patients.

Recently, reports have indicated the relative safety of performing D & E of the uterus on an ambulatory basis to terminate the midtrimester pregnancies. These procedures require special training and experience and should not be undertaken by inexperienced personnel. The use of laminaria tents to dilate the cervix prior to the procedure is reported to be advantageous. Special grasping forceps such as the Sopher forceps are an invaluable aid in the performance of D & E. Anesthesia may be either local or general.

COUNSELING

Unlike most other surgical procedures, the psychosocial dynamics attendant to abortions are such that special counseling is an absolute prerequisite to this procedure. The purpose of this counseling is multiple and includes acquainting patients with the procedure, providing options to abortion, allowing questions to be asked, and providing informed consent. The overall objective is to decrease patients' fears and anxieties. Patients are provided written preoperative instructions and in nulligravidas a laminaria tent is usually inserted into the cervical canal the day preceding the abortion. Also, at that time the history and physical examination should be performed, blood drawn for complete blood

count, blood group, and type, and urinalysis performed. Cervical cytology and gonorrhea cultures should be obtained.

TECHNIQUE

First trimester abortions can be conducted with paracervical block or general anesthesia depending upon cervical softness and dilatation, uterine size, and patient apprehensiveness.

The instruments necessary to conduct a D & C are listed in Table 2. As mentioned, anesthesia can either be paracervical block or general. The patient is placed in the lithotomy position with ankle stirrups. Twenty units of oxytocin are added to 1000 ml intravenous fluids (usually lactated Ringer's solution). The perineum is not shaved, and Betadine (povidone-iodine) solution is used to clean the perineum and vagina. The anterior lip of the cervix is then grasped with a double tooth tenaculum and the uterine cavity sounded. Curved suction cannulas of 8, 10, or 12 mm are available to choose from. Once the suction evacuation has begun, the cannula is not allowed to remain stationary and the intrauterine negative pressure is not allowed to exceed 45 mm Hg. When the evacuation is thought to be completed, a sharp curette is used to "explore" the uterine cavity for abnormalities and possible retained placental fragments which may have escaped the suction apparatus.

If the patient is Rh negative (D^u negative) and unsensitized, she is protected with $Rh_o(D)$ antibody irrespective of her stage of gestation. Upon discharge, she is provided the following written instructions:

1. No sexual intercourse for 3 weeks
2. No vaginal douching for 3 weeks
3. No strenuous activities for 10 days
4. Do not use tampons for 3 weeks
5. You may take a bath or shower at anytime
6. Birth control pills may be started immediately or an IUD inserted after 4 weeks
7. Report any unusual signs or symptoms, e.g., excessive bleeding, severe cramping, etc. (bleeding usually lasts 5–10 days)

Menstrual extraction is an outpatient procedure that has gained some recent popularity. This early abortion procedure is usually limited to patients no more than 7 weeks pregnant (from last menstrual period) or 3 weeks past the first missed period. They, too, should be counseled and have the same preoperative lab tests performed as other abortion patients.

Paracervical block almost always is sufficient. For the apprehensive patient 10 mg diazepam (Valium) in divided intravenous and intramuscular doses can be used. There are several prepackaged disposable kits

marketed for the purpose of menstrual extraction. Suction cannulas of 4–7 mm will usually allow adequate evacuation of the uterine cavity. When evacuation difficulty is encountered, the pregnancy often is beyond the estimated 7 weeks upper limit.

If at first the cervix will not accept a 4 mm cannula, a smaller one can be used or small cervical dialators will be effective. The volume of material removed from the uterine cavity will vary depending upon the stage of gestation; however, this volume seldom exceeds 60 g.

One criticism of this procedure is that very often the patient actually is not pregnant but simply has delayed menses, probably of a dysfunctional origin. Accordingly, it is recommended that one of the early pregnancy tests utilizing the beta subunit of HCG be obtained prior to performing the extraction.

Sterilization

COUNSELING AND PATIENT SELECTION

As with abortion, the psychosocial dynamics associated with sterilization are profound and require special counseling. Sterilization should be offered only to mature women with no further desire of pregnancy. Areas to be covered in the counseling process include: (1) alternative methods of contraception and sterilization, including vasectomy, (2) irreversibility of the procedure, (3) potential failure of the procedure, (4) risks and possible complications, (5) possible change of domestic status, (6) spousal or partner involvement, and (7) freedom to withhold or withdraw consent.

It is understood if the patient is judged to be incapable of comprehending and thus not able to provide an informed consent, she must not be sterilized. Also understood is the need for witnessed documentation of the foregoing and the maintenance of strict confidentiality.

Federally funded sterilization procedures and some state statutes require a specific waiting period between consent and procedure. There exists much disagreement as to how long the waiting period should be, or if indeed there should be one at all. In any case, it is essential for surgeons to be knowledgeable of existing laws. Further, no patient, no matter how sophisticated, should be sterilized without the opportunity to reflect upon her decision in her home environment with those closest to her. She should also be provided her own permanent copy of the consent form.

It is recommended that for outpatient sterilization only American Society for Anesthesiologists class I or II patients be chosen, i.e., a normally healthy patient for an elective operation (see Table I). Any one

of the following conditions constitutes a contraindication to elective sterilization on an outpatient basis: (1) heart disease, (2) convulsive disorders, (3) mental retardation, (4) asthma, (5) diabetes mellitus, (6) hypertension, (7) anemia, (8) anesthetic allergy, (9) pregnancy, (10) intrauterine device in situ, and (11) active steroid contraception. The use of either the IUD or the pill ought to be discontinued at least one full cycle prior to this elective procedure. Also, obesity constitutes a relative contraindication. A weight-height ratio (weight in pounds divided by height in inches) greater than 2.9 can be used as a cutoff point in patient selection.

LAPAROSCOPIC VERSUS MINILAP STERILIZATION

Laparoscopy and minilaparotomy are two rather recently developed techniques that are used for sterilization. Both techniques can be conducted on an outpatient basis and under local anesthesia; the operating times are short, and postoperative recovery normally is short. The question which naturally follows is, which procedure is better? There are no studies which can answer this question. Each procedure has its proponents.

Proponents of the minilap procedure feel it is an easier technique to learn, the equipment required is less expensive, and the laparoscopic complications associated with establishing the pneumoperitoneum and electrical burns are circumvented. Proponents of laparoscopic sterilization generally deny these claims and feel that the postoperative recovery is less difficult for their patients. Also, the potential for electrical burns can be eliminated with the use of silastic bands or spring clips.

Proponents of minilap sterilization point out that cardiopulmonary decompensation, sickle cell anemia, and possibly hernias constitute contraindications for laparoscopic sterilization and that these contraindications do not apply to minilap. All of the stated contraindications for laparoscopy are secondary to the establishment of the pneumoperitoneum. There is agreement, however, that either procedure is effective for female sterilization.

The surgical techniques for each of these procedures should be acquired through a training program which can usually be accomplished in a few days. It is recommended that either procedure be preceded by a dilatation and curettage of the uterus to prevent the possibility of leaving a luteal phase pregnancy.

TECHNIQUE FOR LAPAROSCOPIC STERILIZATION

The basic steps for performing laparoscopic sterilization should include, of course, an adequate pelvic examination, a D & C as mentioned above, the application of a uterine elevator, and an indwelling catheter

placed in the bladder. The steps necessary from this point forward include the establishment of a pneumoperitoneum using the Verres needle. Carbon dioxide is the most commonly used agent for creating the pneumoperitoneum; however, both nitrogen and nitrous oxide have been used. Usually, 2–3½ liters of carbon dioxide flowing at a rate of approximately 4 liters/min and/or an intraabdominal pressure of 20–25 mm Hg are adequate for the introduction of the operative trochar and laparoscope for visualization of the intraabdominal contents. Using the single puncture technique, both visualization and operative procedures can be conducted through this single puncture site; however, when the multiple puncture technique is used a second smaller incision must be made in either lower quadrant using a smaller operative trochar and sleeve, with care being taken to avoid the inferior epigastric vessels; the smaller second trochar tip should enter the peritoneal cavity only under direct visualization through the laparoscope inserted in the upper incision. The second puncture site on many occasions is very beneficial for repositioning pelvic organs that may be abnormally placed or semifixed.

Once the pneumoperitoneum has been established, the intraabdominal pressure is maintained by utilizing a constant flow rate of approximately 2 liters/min, which approximates the absorption rate of carbon dioxide from the intraabdominal peritoneal surfaces, thus maintaining a rather constant volume of gas. At this point, each fallopian tube can be electrocoagulated in at least two places, or silastic bands or spring clips can be applied.

For obese patients or ones who have had previous surgery, open laparoscopy can be done, which allows for the introduction of the trochar and operative sleeve under direct vision. This is accomplished simply by placing a surgical incision in the periumbilical area and either using small retractors or a small proctoscope to visualize the intraabdominal cavity prior to inserting the laparoscope. A purse-string suture is then ased to help seal the defect, thereby maintaining a better pneuperitoneum. A special cannula designed by Hasson can be used to accomplish the same purpose.

Accurate recording of operative findings is a necessity and can be achieved both in a pictorial and narrative fashion. A form suitable for this purpose is shown in Figure 21–1.

TECHNIQUE FOR MINILAP STERILIZATION

The minilap procedure can be done using general or local anesthesia. When done under local anesthesia, an indwelling catheter is placed in the urinary bladder and connected to continuous drainage after D & C has been performed and a uterine elevator has been applied. If the bimanual examination, however, reveals the uterus to be fixed such that

it cannot be repositioned to an anterior location the minilap procedure is canceled; however, if the uterus is freely movable, the abdomen and vagina are prepped with povidone-iodine (Betadine), a paracervical block is done as previously described, a D & C is performed, and a Hulka tenaculum elevator is inserted into the uterine cavity.

Prior to administering the local anesthetic, the patient is usually given fentanyl (Sublimaze) 0.1 mg. For local anesthesia, 10 ml of a 1% solution of lidocaine (Xylocaine) with epinephrine 1:100,000 is used to infiltrate the skin, subucaneous fat, and fascia. A 2½–3 cm transverse incision is then placed 3 cm superior to the upper border of the symphysis pubis in the midline. The incision is opened down to the level of the fascia, which is opened with a transverse 3 cm incision. The rectus muscle is bluntly dissected in the midline to expose the parietal peritoneum, which is opened with a vertical incision 2–3 cm in length and approximately 3 cm above the reflection of the urinary bladder. Adequate Trendelenburg position is obtained, and either tube is exposed by a combination of manipulation and rotation of the uterine elevator. The exposed fallopian tube is then grasped with a Babcock clamp, brought through the incision, and injected with 1 ml Xylocaine in its middle one-third, the area which will be ligated and resected. The fimbriated end of the fallopian tube is identified, and the oviduct is secured with a single transfixation ligature of 00-chromic placed in the middle one-third of the tube. The oviduct is not crushed with an instrument either before or after this ligation. A segment of the tube is excised to serve as a surgical specimen. The same procedure is then applied to the opposite oviduct.

After receiving a correct sponge count and instrument count the peritoneum is closed using a 00-chromic purse-string suture while removing as much CO_2 as possible from the peritoneal cavity prior to closure. This can be accomplished simply by having the assistant press gently but firmly the anterior abdominal wall as the purse-string suture is secured.

The abdomen is closed in layers using a continuous locking 00-chromic suture on the fascia, 000-plain catgut suture in the subcutaneous tissue, and a 00-monofilament nonabsorbable subcuticular suture for the skin. It has been recommended that a nonabsorbable suture be utilized for the skin rather than absorbable suture to help assure patient return for follow-up. Remarkably, the need to have sutures removed looms so very important in the minds of patients that it helps assure return visits.

The patient's vital signs are monitored in the recovery room for at least 2 hours. Analgesics and a light snack or some high caloric liquid are provided as needed. Prior to discharge from the ambulatory facility it is assured that the patient is stable and feels well.

Upon discharge with her escort she is given printed postoperative

GEORGE W. HUBBARD HOSPITAL
OF
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PATIENT'S NAME _____ DATE _____

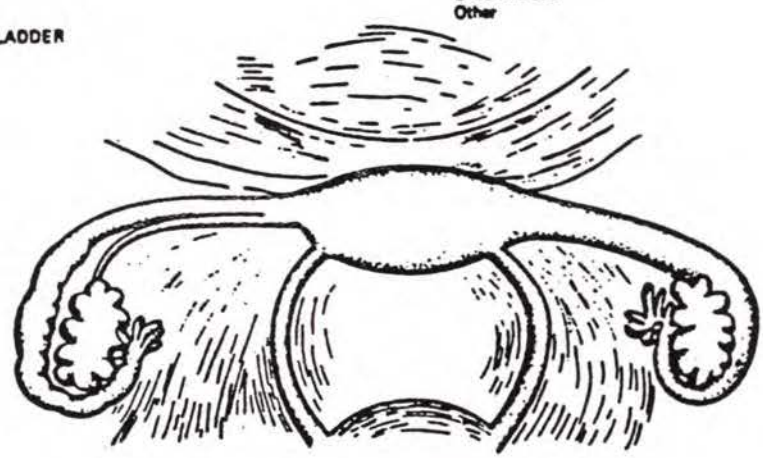
HOSPITAL NUMBER _____ PHOTOGRAPH NUMBER _____

SURGEON _____ ASSISTANT _____ DIAGNOSIS _____

PERITONEAL SURFACES

UTERUS
Size
Shape
Mobility
Fibroids
Adhesions
Endometriosis
Other

BLADDER



LEFT TUBE
Size
Mobility
Adhesions
Patency
Other

RIGHT TUBE

LEFT OVARY
Size
Surface
Adhesions
Other

RIGHT OVARY

LIGAMENTS

CUL DE SAC

OTHER COMMENTS

Fig. 21-1. Form for recording of operative findings.

instructions which advise her to (1) use sponge baths, (2) keep incision dry, (3) avoid heavy lifting, (4) report promptly any bleeding, serious pain, or evidence of infection, (5) resume sexual activities when desired, and (6) return in 1 week for suture removal and again at 6 weeks postoperative for pelvic examination and discharge from treatment.

CONCLUSION

The future of ambulatory gynecologic surgery in this country seems bright. Many of the barriers, both real and imaginary, that have heretofore existed have begun to give way. As these ambulatory procedures become more widely performed and accepted, the safety record which already exists will improve even more.

It must be kept in mind that appropriately performed gynecologic surgery in adequate settings as described in this chapter is a mechanism which will utlimately improve the overall quality of health care provided by our discipline. Of course, as emphasized early in this chapter, the potential economic benefit to the health care system is substantial. The major professional organization of the specialty, The American College of Obstetricians and Gynecologists, supports properly conducted ambulatory surgery. It is now up to the practitioners of this specialty to make this avenue of care more readily available to the female population of this nation.

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SICKLE CELL DISEASE IN PREGNANCY: AN UPDATE

HENRY W. FOSTER, JR.

INTRODUCTION

Although the existence of sickle cell disease dates back into antiquity, it was not until 1910 in Chicago that Dr. James B. Herrick described this disease. His publication recounted a 20-year-old West Indian student with anemia, leg ulcerations, joint and abdominal pains and a "large number of thin, sickle shaped and crescent red blood cells."[1] Numerous publications appeared over the ensuing four decades,[2-17] but the disease was poorly conceptualized and generally remained an enigma until 1949. In that year, Dr. Linus Pauling and associates published their landmark article in *Science*, which elucidated the molecular basis for this disease entity.[18] Pauling's student, Murayama, demonstrated the significance of hydrophobic bonding of amino acids and clarified the molecular interaction and structure of the hemoglobin molecule.[19] Finally, in 1956 Ingram used the "fingerprint" technique, which identified the specific biochemical defect.[20]

More than 150 abnormal hemoglobins have been identified, but the vast majority produce no clinical manifestations. The five hemoglobinopathies seen most often in Afro-Americans involve hemoglobin S and hemoglobin C. The homozygous HbSS and the doubly heterozygous HbSC and HbSThal (thalassemia) hemoglobinopathies are associated with the greatest maternal morbidity and mortality and fetal wastage. The approximate incidence of the various hemoglobinopathies in black Americans is as follows: (1) sickle cell trait, HbAS, one in 12; HbAC, 1 in 60; HbSS, 1 in 600; HbSC, 1 in 850; HbSThal, 1 in 1,600. Hemoglobin C disease, HbCC, the sixth most common hemoglobinopathy, which affects one in 4,400 black Americans, has no significant adverse effect on morbidity and mortality either for mother or for fetus.

IMPLICATIONS OF THE DISEASE

Sickle cell disease is a problem of global occurrence predominantly affecting black Africa and in the western hemisphere. To a lesser extent, Latins and some popula groups adjacent to the Mediterranean Sea and Indian Ocean are affected (Fig. 1). altered hemoglobin molecular characteristic of this disease very likely occurred spontaneous mutation in response to the malaria parasite *Plasmodium falciparum.* believed that the beta chain mutation may have its origin on chromosome num eleven. While this Mendelian trait is generally viewed as an autosomal recessive, in tain circumstances there can be clinical expression in the heterozygous state, Hb. Hence, some authors refer to this inheritance as autosomal codominant.[21]

As implied, genetic resistance to falciparum malaria in man can apparently be c ferred by major genes for abnormal hemoglobins and by other conditions. In additio the protection against falciparum malaria imparted by the sickle cell gene, Allison described a possible relationship between the gene that codes for glucose-6-phosph dehydrogenase (G6PD) deficiency and resistance to malaria.[22] The geographic distri tion of the sickle cell gene and the G6PD deficiency gene can generally be superimpos In the United States, 11 percent of black males carry this red cell abnormality, whic inherited as an X-linked gene. It is fully expressed in hemizygous males, and homo gous females; partial expression is seen in heterozygous females.

The negative effect of sickle cell disease on fertility and pregnancy outcome been long recognized. There appears to be decreased fertility in patients with sickle disease. The reasons for this are multiple and to some extent cumulative. Dela menarche is brought on by a delay in estrogen stimulation. These patients have sex intercourse less frequently because of chronic illness; those who do become pregnant perience an inordinate degree of pregnancy wastage as manifested by an increase in rate of abortion, fetal death, neonatal death, and maternal death.

Table 1 summarizes reproductive outcome data from several published stud



Fig. 1. Geographic distribution of the sickle cell gene.

TABLE 1. Pregnancy Outcome in Sickle Hemoglobinopathies.

Author Year	Type Hemoglobin	Patients	Pregnancies	Spontaneous Abortions	Fetal Deaths	Neonatal Deaths	Perinatal Mortality (%)	Pregnancy Loss Abortion Plus Perinatal (%)	Maternal Deaths
Curtis[23]	SS	9	21	4	16	0	35.3	47.6	0
1959	SC	16	43	7	8	0	22.2	34.9	4
Abrams,	SC	6	30	8	1	0	4.5	30.0	0
Schwartz[24]	SC	3	15	0	0	0	0	0	0
1959									
Anderson	SS	9	17	1	2	0	12.5	17.6	0
et al[25] 1960	SC	7	17	2	0	0	0	11.7	0
McCurdy[26]	SS	19	52	?	?	?	?	34.6*	1
1964	SC	14	59	9	0	0	0	15.2	0
Freeman and	SS	18	41†	11	4	1	15.1	34.1	0
Ruth[27] 1969	SC	23	61	11	2	3	10.0	26.2	0
Fort et al[28]	SS	35	97	15	18	14	39.0	48.4	6
1971	SC	15	35	8	5	2	25.9	42.8	3
Perkins[29]	SS	23	50	10	5	1	15.0	32.0	0
1971	SC	17	59	22	2	1	8.1	42.3	0
Horger[30]	SS	40	45	7	4	0	10.5	24.4	1
1972	SC	9	17	2	5	0	33.0	41.2	3
Pritchard	SS	34	50	16	5	4	26.4	50.1	0
et al[31]	SC	43	78	5	5	2	9.5	15.3	2
1973									
Charache	SS	28	43	11‡	2	2	12.5	34.8	1
et al[32]	SC	10	24	4‡	0	0	0	16.6	0
1980									
	TOTALS	378	854	153	74	30	14.8	30.1	21

* Of the 52 pregnancies, 34 fetuses survived

† 3 sets of twins

‡ Includes an ectopic pregnancy

dating back to the late 1950s.[23-32] The results are as expected: During the 21-year pe 1959–1980, there were 627 live births and 21 maternal mortalities or 33.5 deaths/1, live births, which translates into a maternal mortality rate of 3,350 maternal deaths 100,000 live births. Although Table 1 does not clearly indicate a trend, it does sug that maternal mortality rates associated with sickle cell disease are declining. This appears to be true if the reports of Pritchard[31] and Charache[32] (1973–1980) are c pared with those conducted before 1972. Patients in the Pritchard and Charache rep total 115 or 30.4 percent of all patients. However, Pritchard and Charache report on of the 21 maternal deaths or, 14 percent. It is likely that this apparent trend will be roborated as new data on this subject continue to accumulate.

The excessive perinatal mortality rate of 148 warrants comment, particularly disproportionate contribution caused by fetal deaths. In the normal population, f deaths account for substantially less than one-half of the perinatal mortality. Here t contribution is 71.1 percent. Such outcome is a reflection of the morbid state of the pectant mother with this disease. This marked debilitation of the mother is furt manifested by the extreme pregnancy loss associated with sickle cell disease. The te "pregnancy loss" includes observed spontaneous abortions in addition to fetal dea and neonatal deaths, and is calculated as follows:

$$\text{pregnancy loss} = \frac{\text{abortions + perinatal deaths}}{\text{total pregnancies}}$$

$$\text{or} = \frac{153 + 104}{854} = 30\%$$

This loss among mothers with sickle cell disease is two and one-half times greater th that seen in the normal population. It is apparent that the disproportionate contributi of spontaneous abortion to the overall pregnancy wastage in this disease often is not fu recognized.

CHEMISTRY OF THE HEMOGLOBIN MOLECULE

Hemoglobin is a conjugate of a pigment, heme, and a protein, globin, and is the oxyg transporter of the erythrocyte. The heme portion of the molecule is a polyvalent cor pound consisting of protoporphyrin combined with iron in the ferrous state; it impar the characteristic red color of hemoglobin. The globin component is a polypeptide co sisting of two pairs of amino acid chains with a total of 574 amino acids per hemoglob molecule. There are two alpha and two beta chains, having 141 and 146 amino ac residues, respectively.

Nomenclature

Nomenclature of hemoglobinopathies is based upon the sequence of amino acid residu (Table 2). In adult hemoglobin the polypeptide chains are of four types: alpha (α), be (β), gamma (γ), and delta (δ). During fetal development a fifth type of polypepti

TABLE 2. Hemoglobin Nomenclature.

HEMOGLOBIN TYPE	HEMOGLOBIN DEFECT	GLOBIN STRUCTURE	WRITTEN DESIGNATION
EARLY FETAL	NONE		
EARLY FETAL	NONE		
FETAL	NONE		
NORMAL ADULT	NONE		
NORMAL ADULT	NONE		
SICKLE CELL TRAIT	β CHAIN SUBSTITUTIONS		
SICKLE CELL ANEMIA	β CHAIN SUBSTITUTIONS		
Hb-S-C DISEASE	β CHAIN SUBSTITUTIONS		
Hb-S-THALASSEMIA	β CHAIN SUBSTITUTIONS. DECREASED β CHAIN PRODUCTION		

chain exists and is designated as epsilon (ε) (Fig. 2). Epsilon chains are produced only in the first trimester. Their erythropoietic organ is the yolk sac. The two chains of hemoglobin formed utilizing epsilon chains are called Gower-1 and Gower-2. The production of gamma chains also appears in the first trimester and remains at peak levels until shortly before birth. Gamma chains are necessary for the production of fetal hemoglobin and their erythropoietic organs are the spleen and liver. It has been suggested that the high spontaneous abortion rate that occurs near the end of the first trimester may result from a faulty genetic switching mechanism that controls hemoglobin synthesis.[33] To progress from Gower hemoglobins to fetal hemoglobin requires action of the repressor gene for epsilon chains and the activator gene for gamma

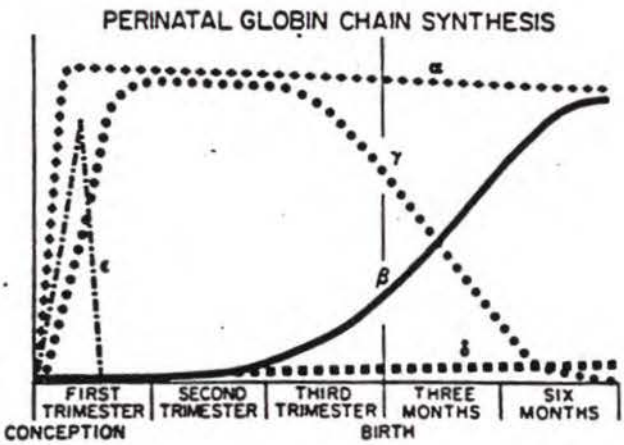


Fig. 2. Perinatal globin chain synthesis.

chains. If the repressor gene for epsilon chains operates normally but the activator gene for gamma chains fails, HbF synthesis does not occur and Gower hemoglobin levels fall rapidly. The result is anemia and abortion or fetal death.

Molecular Interaction

In normal circumstances, the erythrocyte is a biconcave disc, membranous in make-up and characterized by extreme plasticity. Such an arrangement is essential for erythrocytes to flow through the finer passages of the microcirculation. However, erythrocytes that contain S hemoglobin lose this plasticity when subjected to low oxygen tension, acidosis, and dehydration, and hence, assume their peculiar elongated or sickle shape. When this sickling occurs in or proximal to the microcirculation, the result is occlusion with infarction distal to the site. Clinical symptoms obviously will correlate with the extent of the sickling and the organ involved.

The extent and ease with which sickling occurs is determined in great part by the amount of S hemoglobin within the erythrocyte: In sickle cell disease S hemoglobin accounts for nearly 100 percent. In sickle cell trait, only 20 to 45 percent of the erythrocyte's hemoglobin is of the S type and this arrangement offers substantial protection against severe sickling. The mechanism by which this protection is provided is noteworthy (Fig. 3). On average, each erythrocyte contains approximately 270 million hemoglobin molecules. The mechanism ultimately responsible for sickling is a process referred to as molecular stacking and is the result of the formation of hydrophobic interactions between the beta chains of a sickle hemoglobin molecule and the alpha chains of either a normal hemoglobin molecule or another sickle hemoglobin molecule. When another sickle hemoglobin molecule is hydrophobically bound, its beta chains too can again form a bond with yet another alpha chain thus leading to molecular stacking. The extent to which this can occur in the erythrocyte that contains only S hemoglobin molecules is virtually endless. With severe sickling as seen with the disease microfibrils are first formed and later grow into what is termed microcables. Most researchers believe that 14 strains of microfibrils uniquely combine to form a long microcable.

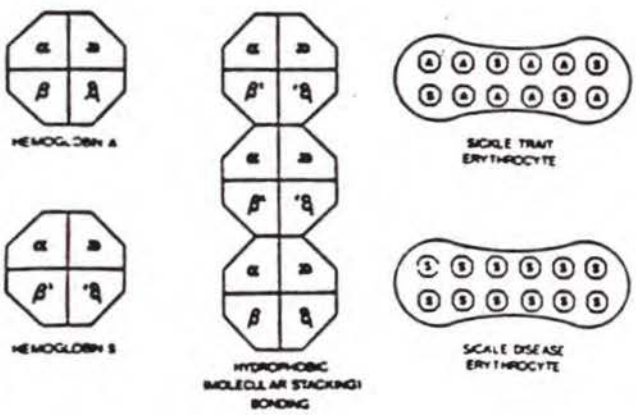


Fig. 3. Abnormal β chains and α chains hydrophobically bond to effect molecular stacking. In the sickle trait erythrocyte there is only one chance in three that the bond will involve an HbS molecule. In the sickle disease erythrocyte the chance is 100 percent.

However, within the erythrocyte from an individual with the trait, approximately two-thirds of the molecules contain no S hemoglobin and thus, cannot continue the stacking process, which seems to occur on a random basis.

The kinetics of HbS polymerization have been intensely studied, and recent findings offer promising new approaches to therapy.[34-37] The kinetic hypothesis relates to the time required for the erythrocyte to release its oxygen to the tissues. In the arterial system erythrocytes contain an oxygenated solution of hemoglobin (either HbS or HbA). As the erythrocyte squeezes through the narrow microcirculation to reach the venous system, its oxygen is released to the tissues. Under normal physiologic conditions, the speed at which the erythrocyte releases its oxygen to the tissue (delay time) is the same order of magnitude for HbS as it is for HbA. Hence, under most circumstances, if HbS-containing erythrocytes sickle, they do so only after they leave the capillary and will regain their normal morphology and flexibility upon reoxygenation in the lung. Under circumstances of stress, it is postulated that sickle erythrocytes release their oxygen sooner (a shortened delay time) with resultant polymerization and sickling before they leave the capillary. Hence, loss of flexibility occurs in the microcirculation or before the microcirculation is entered, and blockage results with subsequent infarction. The kinetic hypothesis argues that the delay time, relative to capillary transit time, is the clinical variable that determines the clinical severity of sickle cell disease. Numerous agents are now being actively studied in vitro which are effective in increasing the delay time thus postponing polymerization and sickling until *after* the microcirculation has been traversed; these agents should be effective in vivo.

SCREENING AND COUNSELING

Because of the wide prevalence of the trait among people of African descent, *voluntary* mass screening should be encouraged and fostered through well structured provider and consumer education programs. In the late 1960s when an awareness of the sickle cell phenomenon was emerging, a lack of education of both consumers and providers resulted in much unnecessary and unfortunate social and economic harassment varying from such misconceptions as believing the condition was contagious, to insurance carriers canceling coverage on individuals possessing the sickle cell trait. Through time and better education, perhaps premarital and school screening programs will become routinely accepted and widespread.

Choice of Screening Test

Proper screening for abnormal hemoglobins is best accomplished by hemoglobin electrophoresis followed by solubility testing (Fig. 4). These tests once considered elaborate can be obtained through almost any clinical laboratory and are cost-effective when the wide prevalence of abnormal hemoglobinopathies is considered. Further, there is no need for repeated tests in subsequent pregnancies.

As a practical matter, routine electrophoretic screening cannot always be accomplished. The use of one of several commercial kits is therefore an alternative. These

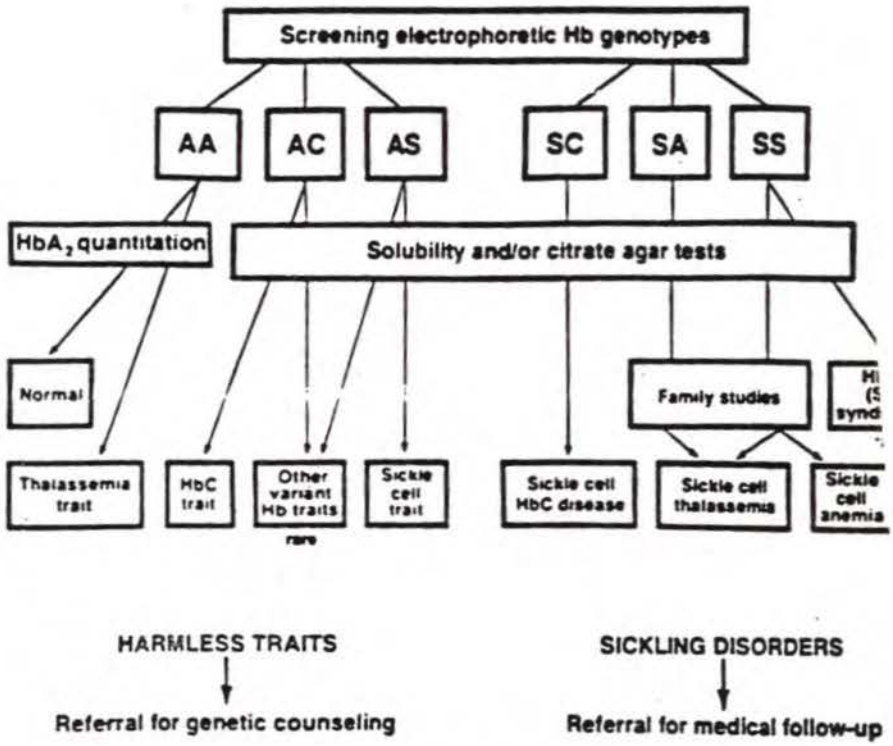


Fig. 4. Hemoglobinopathy screening and follow-up.

kits utilize colorimetric indices that are easy to read; false positive results do oc however, and any standard sulfite test should be performed on all positive sampl identify these spurious results. When the metabisulfite results are positive, t specimens should then be subjected to agar or gel electrophoresis to document presence of HbS and to distinguish trait from disease. It should be pointed out sodium metabisulfite is not adequate to detect hemoglobin C (except C-Harlem), o again making the case for the use of electrophoresis as the basic screening approac

Solubility testing after electrophoresis helps to identify many rare hemoglo variants that have the same electrophoretic mobility as HbS. When results are uncle refined confirmatory tests become necessary.

Counseling

Proper counseling for pregnant patients is essential to provide education, reassuran and optimal medical outcome. Audiovisual material is useful in explaining the gen implications of the disease. Genotype charts, which display percentage inherita odds, are particularly helpful. The most frequent risk is the trait-by-trait (HbAS/A

mating; it carries a 25 percent chance of producing a child with the disease state (HbSS) and a 50 percent chance of the trait (HbAS). When either parent has the disease (HbSS) there is no chance for any offspring to escape the inheritance of S hemoglobin irrespective of the genotype of the other parent.

On occasion, the genotype of the father is unknown. In such circumstances it is possible nonetheless to predict the inheritance percentage odds. In the mother who carries the trait, where the genotype of a black father is unknown, the chance of the offspring inheriting the trait is 4 percent and the disease is 2 percent. These results are derived from the known 8 percent prevalence of the trait in this country's black population.

The ultimate responsibility in counseling pregnant patients with sickle cell disease (HbSS) is to assure their full comprehension of the risk of maternal death. With exemplary care, the maternal mortality rate will probably be on the order of 1 to 2 percent. While this is a formidable ideal, the decision to risk a pregnancy is an option that can justifiably be chosen by the expectant mother. There are probably few life experiences more rewarding than reproducing one's own kind.

Intrauterine and Neonatal Diagnosis

The ability to ascertain the fetal hemoglobin status *in utero* extends our capacity to provide genetic counseling. Such capability not only affords the option of pregnancy termination, but also provides an early opportunity for patient education.

In the past, efforts in antenatal diagnosis have been carried out by obtaining fetal blood samples through the technique of fetoscopy.[38] Fetal blood samples are obtained by aspiration of the placental or umbilical vein. It now appears, however, that interest in this technique is waning for the problems associated with *in utero* fetal blood sampling have been significant. For example, a fetal loss rate of up to 10 percent has resulted from postaspiration fetal hemorrhage;[39] moreover, the procedure cannot be attempted if the placenta occupies the anterior uterine wall, and there have been problems with sample contamination by maternal blood.

Rather recently investigators have described a technique using uncultured fetal cells obtained by amniocentesis to diagnose sickle hemoglobinopathies and thalassemia. This technique involves gene mapping using the polymorphism of a restriction endonuclease site to diagnose both sickle cell trait and sickle cell disease.[40] Although only 60 to 70 percent of patients with the sickle gene exhibit this polymorphism, in those who do, the reliability is excellent.

At birth, hemoglobin electrophoresis should be carried out on cord blood samples. An early diagnosis of sickle cell disease should alert the parents and the pediatrician to watch for signs and symptoms of painful or life-threatening complications. Prompt treatment can minimize their effect. Because of the high percentage of HbF present at birth, the diagnosis of sickle hemoglobinopathies presents certain technical difficulties. Nonetheless, a definitive diagnosis can be established using agar gel electrophoresis at pH 6.2.[41]

CLINICAL MANAGEMENT

Sickle Cell Trait

Discussion of the clinical management of pregnancy and sickle hemoglobinc should begin with consideration of the sickle cell trait. There are no documented which show any increase in either maternal or perinatal mortality. There is, hc some suggestion as to increased morbidity as it relates to the urinary tract.[42] T been manifested by gross hematuria, asymptomatic bacteriuria, and pyelonej Over time patients with trait may also develop hyposthenuria. There is at theoretical explanation for this occurrence.

As red blood cells flow from the kidney cortex to the medulla, there is a progi increase in osmolarity (up to 1200 mOsm) as the medulla is reached. This often i in sickling, stasis, ischemia, and, in time, permanent structural damage. Since ap imately 14 percent of the nephrons are juxtamedullary, hyposthenuria can bec clinical manifestation.

Pregnant sickle cell trait patients should have urine cultures and sensitivity st done. Positive cultures should be treated with appropriate antibiotics for three w Reculture should then be taken and if results are negative, these patients shou maintained on methenamine mandelate (Mandelamine, Manese, Mandacon).

There has been one retrospective study which suggests an increased inciden premature rupture of the membranes in patients with sickle cell trait.[43] Howeve other report of this phenomenon has appeared.

Sickle Disease-Antepartum Management

The contemporary management of sickle cell disease in pregnancy provokes m debate. However, such a response is to be expected in view of our lack of a knc curative therapy. Some of the issues in question relate to the use of blood transfusic supplemental iron, timing and route of delivery, anesthetic choice, and contracept and sterilization approaches.

Every pregnant patient with sickle cell disease should be hospitalized at the earli opportunity. At this time, a baseline evaluation of the patient is conducted and she a her family can be educated with particular emphasis being placed on nutrition and fection prevention. It is axiomatic that the importance of patient compliance be fu understood and appreciated by all concerned. Needed consultations are obtained, e. ophthalmology, nephrology, and all routine antenatal measures are begun.

The value of the use of supplemental iron in these patients remains in question. the past, iron was usually withheld and many thought its use may increase the risk hemochromatosis. However, this fear appears unjustified given the short duration pregnancy. Moreover, one rather recent study revealed that 65 percent of sickle disease patients show an iron deficiency anemia.[44] Also, the amount of iron required the developing fetus may exceed that available in the diet. Lastly, assessment of i stores to determine therapy is not always practical and often of questionable reliabi

except in the face of severe depletion. For these reasons, supplemental iron in some form is recommended.

Prophylactic Partial Exchange Transfusion. Probably the most controversial issue of all for these patients is that of prophylactic partial exchange transfusion (PPET). The risk-benefit ratio is unclear and needs further investigation. It was for this reason that in 1979 NHLBI sponsored a consensus development conference at the National Institutes of Health.[45] The work groups at that conference focused on four subject areas: Need for further research, clinical research approaches, perinatal considerations, and sociomedical issues. The two-day meeting concluded that at present insufficient evidence exists about PPET therapy to advocate its routine use for treatment of all pregnant patients with sickle cell disease. The issues raised can only be answered through a randomized multicentered collaborative study.

The first published suggestion that exchange transfusions might be used for prevention as well as treatment for sickle cell disease appeared in 1963.[46] More recently, several authors have recommended prophylactic exchange transfusion.[47-51] The advantages and disadvantages of this approach, both real and theoretical, are several (Table 3); but many are not in accord with the recommendation for PPET, and their reservations have merit.[52] With PPET, large numbers of blood cells are transfused; hence, isosensitization remains a serious potential threat to patients. They have been known to become severely sensitized and virtually incapable of being compatibly cross-matched. In the face of life-threatening conditions where transfusions are essential, the results could be fatal.

Other risks are minimized by the use of washed, buffy-coat-poor, red blood cells, which decreases the number of white blood cells transfused—the most likely cause of a transfusion reaction. The washing of red blood cells also reduces significantly the risk of hepatitis. Although any of these potential problems may occur, it should be pointed out that in this era of exemplary blood banking techniques, the likelihood of their occurrence is small. Further, to reduce the chances of atypical antibody formation, consanguineous family members who have no sickle hemoglobin should be sought as blood donors.

The potential problem of iron overload seems more theoretical than real. With PPET, iron is removed, albeit a smaller amount than that which is replaced. Beyond

TABLE 3. Prophylactic Partial Exchange Transfusion.

Possible Advantages	Possible Disadvantages
Reduced HbS cells	Incompatibility
Increased HbA cells	Transfusion reaction
Suppressed HbS erythropoiesis	Anaphylaxsis
Increased oxygenation	Hepatitis
Increased sense of well-being	Isosensitization
Improved perinatal outcome	Volume overload
Reduced infections	Febrile reaction
Reduced crises	Hemochromatosis
	Premature labor
	Psychological dependence

this, however, females are relatively protected by their periodic blood loss associat with menstruation, iron loss to the fetus during pregnancy, and the blood loss that a companies parturition.

The question of volume overload must be addressed. Most experience, thus fa has utilized a manual method to conduct PPET (Table 4).[33,34] Although problems wi volume overload using this protocol have been very infrequent, they occur nonethele Recent experience with PPET employing automated erythrocytopheresis suggests th this problem, and others associated with the technique of PPET, are even less likely.[35] comparison of the two techniques may well be a part of the structured protocol of multicenter study being proposed by the National Institutes of Health.

Other Clinical Considerations. Patients with sickle cell disease should have cesarea section performed only for obstetrical indications. Indeed abdominal delivery associated with a greater likelihood of postpartum complications such as infectio crisis, and thromboembolic disease. Sickle cell disease patients should be followed du ing the antenatal period with biweekly visits until the conclusion of their thirty-sixt week of gestation. At this time, nonstress tests should be conducted on a weekly bas until the onset of labor. If the nonstress test is positive, the stress test should be used, an if it too is positive, pregnancy should be terminated by the abdominal route. Howeve if these tests remain normal, the onset of labor is awaited. For patients whose pregnar cies extend beyond the forty-first week of gestation, labor is induced and electronic fet monitoring is used.

Labor and delivery in these patients, whether spontaneous or induced, should b managed essentially the same as labor in patients with cardiac disease. Oversedatio must be avoided and oxygen administered. If great caution is taken, most forms c anesthesia can be used. However, epidural anesthesia is preferred. Its use obviates th need for narcotics; hence, fetal depression is less. The use of episiotomy and low forcep to shorten the second stage of labor is recommended.

Fluid and electrolyte replacement during labor and the postpartum period, critical factor in these patients, is easily mismanaged. Negative fluid balance ofte characterizes these patients. Most have impaired renal concentration capacity and thu excrete excessive quantities of urine, and, as do most patients in labor, they lose thei appetites, which results in impaired fluid and food intake. Intravenous fluid intak should include ample amounts of water/dextrose solution and adequate electrolyt replacement. These patients tend to have metabolic acidosis, which can be correcte

TABLE 4. Guide for Prophylactic Partial Exchange Transfusion.

1. Measure Hct, HbA, type and x-match, bilirubin reticulocyte count, LDH, urine hemoglobin
2. Infuse 300 ml of normal saline (5 ml/min)
3. Phlebotomize 500 ml blood in the opposite arm (10 ml/min)
4. Transfuse 2 units of packed cells (buffy-coat-poor washed red cells) (5 ml/min)
5. Repeat steps 2, 3, and 4
6. Measure Hct and HbA by quantitative hemoglobin electrophoresis 12 hours later (therapeu objective: HbA >60%, Hct >35%)
7. Repeat step 1 monthly thereafter
8. Repeat steps 2, 3, and 4 if:
   (a) HbA is < 30% or Hct is < 25%;
   (b) crisis occurs;
   (c) labor ensues;
   (d) surgery becomes necessary

with lactate and bicarbonate solution and the effects monitored with serum electrolyte studies.

During the postpartum period, patients must be monitored carefully for signs and symptoms of infection and crisis. Urinary catheterization should be avoided if possible and broad-spectrum antibiotics administered for at least 96 hours postpartum. Congestive heart failure is not uncommon in the postpartum period and digitalis should be given if necessary.

As mentioned earlier, hemoglobin electrophoresis should be carried out on cord blood samples. The postpartum period is also a convenient time to administer to the mother the rather recently developed polyvalent pneumococcal vaccine. This vaccine, indicated for all patients with sickle cell disease, should not be given during pregnancy or to children less than six months of age. Revaccination is recommended at three-year intervals.

The occurrence of crises in pregnant patients with sickle cell disease is clearly a serious complication; however, crisis management in these patients differs little from procedures employed with nonpregnant patients. Most crises are of the vasoocclusive type and produce intense pain. Aplastic (aregenerative) crises are only about one-fifth as common. Acute sequestration crises, where a large amount of blood is trapped primarily in the liver and spleen, are mostly confined to childhood. The basic component of crisis management includes analgesics, PPET, intravenous fluid and electrolyte replacement, oxygen administration, and elimination of infection. One must keep in mind, however, that the signs and symptoms of crises can be virtually indistinguishable from those of an acute abdominal condition, particularly appendicitis and ectopic pregnancy, which must always be ruled out.

Fertility Control

Choosing the proper method of contraception for patients with sickle cell disease is at best an empiric exercise.[36] The most effective agents, oral contraceptives, are contraindicated—at least theoretically—because they increase blood coagulability thus lowering the threshold for crises. Current data show a sevenfold increase in the risk of death from thromboembolic disease for oral contraceptive users over nonpregnant nonusers with the increase in the risk of death being 15 per million and 2 per million respectively.[37] A prior history of deep vein thrombosis is a contraindication to the use of the pill and it is believed by some that sickle cell disease also constitutes a contraindication to the use of estrogen.[38]

Progestin-only contraceptives such as the minipill and long-acting intramuscular progesterone have been suggested for patients with sickle cell disease. Theoretically, this estrogen-free medication should pose a lesser threat, but there are no good data that clearly exempt progestins as a causative or contributory factor to the thromboembolism. It has also been suggested that the metabolism of progestins may involve some conversion to estrogen.

There also is little consensus among practitioners on the role of the intrauterine device (IUD) in sickle cell disease patients. To make a judgment requires an evaluation of the known complications associated with IUDs. The two complications that bear the

greatest relevance to patients with sickle cell disease are infection and excessive bleeding. Irrespective of the technique used for insertion, bacteria are introduced into the uterine cavity, and, although the bacterial count usually decreases after a few weeks, the endometritis persists as long as the device is in place. Moreover, most serious complications from IUDs, including death (0.3 to 1.0 per 100,000 users per year), are related to sepsis.[59] Because of the known adverse effect of infection on sickle cell disease patients, this feature, it seems, renders the IUD inappropriate for them.

It is clear that contraceptive effectiveness and safety bear an inverse relation to each other. Hence, we are left to consider the less effective but safer barrier methods of contraception. Condoms, diaphragms, foams, and jellies are acceptable forms of contraception in these patients. With adequate patient education, the barrier contraceptive recommended for patients with sickle cell disease is a spermicidal gel containing nonoxynol-9, used preferably with a diaphragm. In addition, the patient is taught how to calculate her probable date of ovulation; at this time her partner is advised to use a condom during the three days before, the three days after, and on the calculated date of likely ovulation (total of 7 days). Although this contraceptive approach may seem complex, with adequate education patient compliance can often be achieved in these usually highly motivated patients.

The use of abortion solely as a form of contraception, although acceptable in some parts of the world, has not become prevalent in the United States. Clearly, this would not be ideal for patients with sickle cell disease. Such an approach would necessitate an operative procedure through up to 18 weeks' gestation; thereafter, termination procedures would require the use of prostaglandin or hypertonic saline infusions, with their inherent risk of complications and possible subsequent abdominal surgery.

Many sickle cell disease patients who have a successful pregnancy choose sterilization. The procedure should be performed after the six-week postpartum period, with either regional or local anesthesia. Laparoscopic sterilization is not recommended;[60] this procedure compromises pulmonary aeration because of the relatively high fixed position of the diaphragm. Furthermore, in 90 percent of laparoscopic procedures conducted in this country, carbon dioxide is used to establish the pneumoperitoneum, which results in hypercarbia.[61] The elevated pCO_2 and lowered pH have been shown to be the result of CO_2 absorption from the peritoneal surface and not necessarily of improper ventilation during anesthesia.[62] Accordingly, laparoscopic sterilization for these patients is not recommended. As an alternative, the interval minilap sterilization procedure, using local anesthesia, is recommended.

SICKLE CELL DISEASE FUNDING

In view of the country's current economic condition, the future funding status of sickle cell disease programs from a public standpoint must be characterized, at best, as uncertain. The federally funded National Sickle Cell Disease Program was initiated in 1971 following the President's health message to Congress, which targeted sickle cell anemia as a major health problem. This pronouncement led to passage of the National Sickle Cell Anemia Control Act (P.L. 92-294) and provides for a national program of research, training, education, and screening and counseling in sickle cell disease. In

1973, the hemoglobinopathy training program at the Center for Disease Control was added.

For a period of time thereafter, the funding picture continued to be brighter. In 1970, approximately one million dollars annually was allocated, routed through the National Institutes of Health and distributed to a few institutions for mostly basic research. The President's budget added an additional 5 million dollars to this base, which was later increased to 10 million dollars in 1972. Subsequent years saw the annual support increase to 16 million dollars in fiscal year 1977 and 30 million dollars thereafter. It now seems apparent, however, that this trend of increasing appropriations for sickle cell disease will be reversed. At this juncture, the level of future support for sickle cell disease programs is unknown. Hence, the National Sickle Cell Disease Program to decrease the frequency, morbidity, and mortality of sickle cell disease through programs of research development and service demonstrations appears in jeopardy.

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OBSTETRICS - GYNECOLOGY

Hematologic Problems in Pregnancy

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Chapter 10

Thalassemia

Henry W. Foster, Jr., MD
Robert Lownes, MD

The thalassemia syndromes are inherited disorders classified among the hypochromic anemias. The defect involves the rate of production of hemoglobin. It has been shown that the microcytic, hypochromic anemia seen in thalassemia is characterized by excessive ineffectual erythropoiesis, with rapid destruction of newly formed erythrocytes.[1-3] This unbalanced rate of globin chain synthesis results in aggregates of protein, precipitating within the erythrocyte as inclusions, with resultant damage to the red cell membrane. In α thalassemia, beta chain inclusions occur, and in β-thalassemia, alpha inclusions accumulate. The damaged cell becomes predisposed to premature destruction in the reticuloendothelial system.

The implications of the thalassemias as they relate to pregnancy outcome include a wide spectrum ranging from almost uniformly fatal hydrops fetalis to essentially uncomplicated pregnancy. Concern must be for the potential for homozygous progeny from heterozygous mating. Frequent significant obstetrical complications occur when the thalassemia defect is coupled with the sickle gene (Chapter 9). If for no other reason, the search for the thalassemia defect in obstetric patients becomes very important from the aspect of genetic counseling.

Genetic Defect. All forms of thalassemia are inherited as an autosomal recessive trait. There are four genes controlling alpha chain synthesis in Caucasians and Orientals; blacks have two, three, or four genes that may or may not combine for α-thalassemia. There are two genes each for beta and delta chains, and four genes for gamma chains. The beta, delta, and gamma genes are closely linked on chromosome 11.[4,5]

Quantitative deficiency of alpha or beta globin messenger RNA (mRNA) resulting in decreased synthesis of alpha or beta chains is a common defect in most of the thalassemia syndromes. Gene deletion is responsible for most α-thalassemia syndromes which results in decreased mRNA and alpha chain synthesis.[6] Three variants of β-thalassemia are distinguishable on the basis of the severity of expression: β_m, β^+, β^{++}. In β-thalassemia there is complete absence of beta chain synthesis. β^+ and β^{++} thalassemia homozygotes synthesize beta chains at a low rate.

Unlike α-thalassemia, a gene deletion has not been demonstrated in β-thalassemia. Beta thalassemias may be the result of a diminished rate of translation at

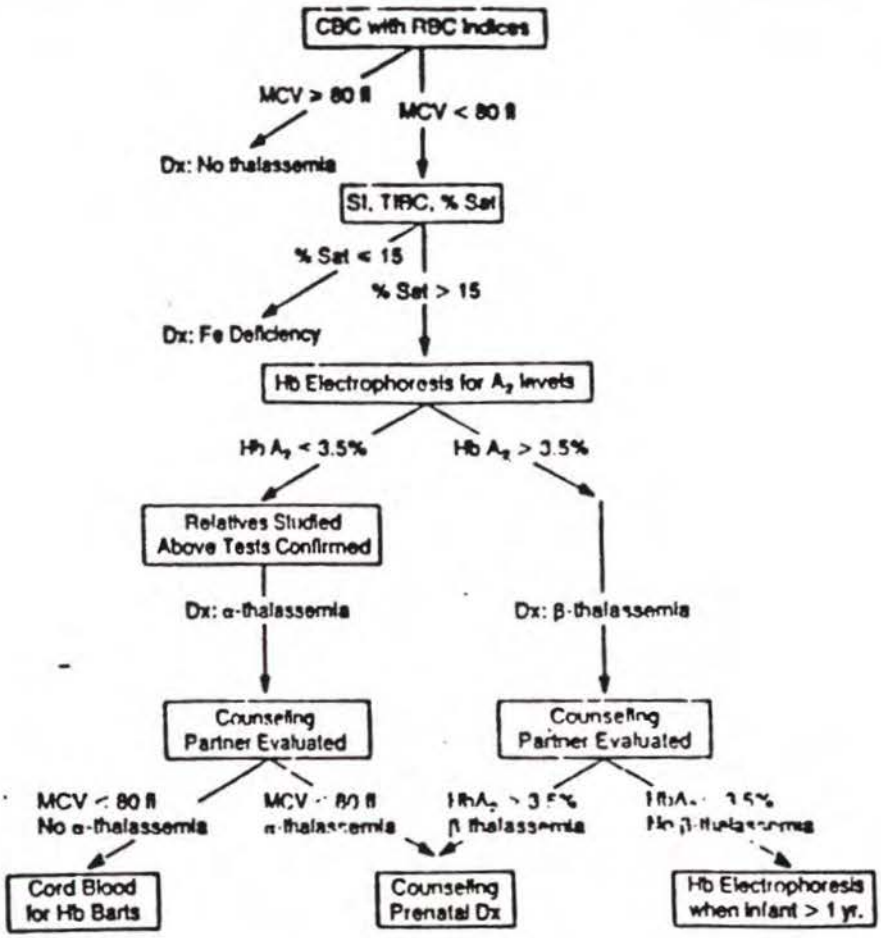
the ribosomal level, or a diminished rate of transcription or faulty transcription of the DNA code into mRNA.

Screening. In the past, little effort was made to screen the general obstetric population for the presence of thalassemia, except perhaps as it related to sickle-cell disease. Failure to diagnose thalassemia in otherwise uncomplicated pregnancies was considered to be of no great consequence. With the capacity for reliable antenatal diagnosis both in homozygous and heterozygous states, this rather casual approach is no longer acceptable. At least 100,000 children die annually worldwide as a consequence of β-thalassemia.[4] Homozygous α-thalassemia produces a uniformly fatal in utero form of hydrops fetalis, rendering such a pregnancy futile. Such pregnancies are associated with an increased incidence of preeclampsia which carries a significant unjustifiable risk; the continuation of this type of pregnancy is unwarranted, given the availability of antenatal diagnosis and the option of pregnancy termination.

The obstetric population is an ideal group to screen for genetically propagated incurable diseases. A good screening method should be simple, economical, acceptable to the patient, and reliable, with virtually no false-negatives and few false-positives. Various methods and schemes for thalassemia screening appear in the literature. Most are rather cumbersome, require the use of moderately involved mathematical formulae, and are not specifically designed for pregnancy. According to Healey, thalassemia is said to exist in an individual in whom the function $(0.23 \times MCV) - (.022 \times RBC) - 6 (0.93 \times Hb) - 3 < 0$.[6] The formula was simplified by England and Fraser to $MCV - RBC - 5\ Hb - 3.5 < 0$.[7] Mentzer recommends using the ratio of MCV:RBC with values less than 13 corresponding to patients with thalassemia. Shine and Lal have developed a heuristic method which they believe yields the lowest false-negative rate, and an acceptable number of false-positives: $2\ MCV \times MCH < 1530$.[9]

The screening program described by Alger has the basic criteria for a good screening method, and is designed expressly for screening a pregnant population.[10] This approach uses red cell indices (Figure 10-1). If the mean corpuscular volume (MCV) is 80 fl or greater it is concluded that thalassemia is not present and no further studies are necessary. When the MCV is less than 80 fl it becomes necessary to rule out iron deficiency anemia as a cause of microcytosis. This can be accomplished by determining the serum iron (SI) and percent saturation. The total iron binding capacity (TIBC) is less useful in making the distinction; the usual reciprocal relationship between TIBC and iron stores is inconsistent in pregnancy.[11,12] If the SI is greater than 50 μg/dl, and the percent saturation is greater than 15%, iron deficiency is ruled out. Hemoglobin electrophoresis is performed. The amount of hemoglobin A_2 is quantified by densitometry, with a level greater than 3.5% diagnostic of β-thalassemia trait. When iron deficiency and β-thalassemia trait co-exist, family history, peripheral smear examination, and measurement of the red cell distribution width are helpful. A course of iron therapy will raise a falsely lowered hemoglobin A_2. The most severe form of α-thalassemia compatible with extra-uterine life results from deletion of three genes

FIGURE 10-1 Thalassemia Screening Protocol



and is designated as hemoglobin H disease. These patients also possess hemoglobin Barts which aids in diagnosis.

All too often microcytosis is found and patients are summarily treated for iron deficiency with no attempt at further evaluation. This can lead to iron overload, particularly when the route of iron administration is parenteral

Counseling. Proper counseling for pregnant patients is essential to provide education, reassurance, and optimal medical outcome. Once the diagnosis has been established and the patient grasps potential implications, it becomes necessary to counsel and evaluate her partner. A complete blood count and hemoglobin electrophoresis are performed. If he is diagnosed as a carrier of a like thalassemia

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trait, or is heterozygous for a hemoglobinopathy, which coupled with the trait of his mate can cause clinical difficulty, the couple must be provided with genetic counseling and offered antenatal diagnosis, with the option of pregnancy termination. A relatively frequent example of a doubly heterozygous state is sickle β-thalassemia. Other combinations with thalassemia include C, D, and E. All are quite rare in pregnancy. Patients with HbD/Thal and HbE/Thal have a clinical course similar to that of Cooley's anemia, and hence, rarely become pregnant. A mild anemia accompanies HbC/Thal during pregnancy.

Antenatal Diagnosis. In the past, antenatal diagnosis of thalassemia and hemoglobinopathies has depended on globin synthesis studies of fetal red cells obtained by fetoscopy, with aspiration of the placental or umbilical vein.[13,14] Although this method has been successfully used in over 1,000 cases, it does have several significant limitations. The technique of fetoscopy is tedious, requires great skill, and is available in only a few centers. Fetal loss as great as 10% has resulted from post-aspiration hemorrhage.[15] The procedure cannot be attempted if the placenta is anterior, and a potential exists for sample contamination by maternal blood. In contrast, amniocentesis is a relatively safe procedure that can be done in most centers. The best example identified by amniocentesis is α-thalassemia due to gene deletion. In the homozygous condition where all four genes are deleted, no alpha chains are produced, and the fetus is incapable of synthesizing HbF, or any adult hemoglobin. Hemoglobin H disease results from deletion of three genes. In thalassemia minor (α-thalassemia-1) two genes are absent. A single gene deletion (α-thalassemia-2) is known as the "silent carrier" state and is clinically undetectable.

One technique for antenatal diagnosis of α-thalassemia involves amniocentesis, cell culture, and measurement of the number of intact alpha globin structural genes present in the cellular genome using molecular hybridization.[16] Using reversed transcriptase, a viral enzyme which transcribes DNA from RNA, complementary alpha DNA can be transcribed from alpha mRNA. The transcribed cDNA is complementary to, and has the capacity for, binding to alpha-globin structural genes existing in cells. The speed at which the cDNA binds to DNA from amniocytes is proportional to the number of copies of alpha structural genes present in cells, thus distinguishing the homozygotes from the carriers or normal states.

Recently investigators have begun to utilize a technique involving uncultured amniocytes and gene mapping. This approach uses restriction endonucleases which cleave DNA within specific base sequence recognition sites.[17] The repository of these enzymes is growing (Table 10-1). DNA fragments can be separated by agar gel electrophoresis, and the number and type of fragments allow for genome mapping. This technique has been used to verify deletion of alpha sequences in homozygous α-thalassemia. Also, some varients of β-thalassemia have been shown to be associated with DNA mutations that can be detected by certain restriction endonucleases.[18] Further, according to Phillips, 70% to 75% of pregnancies at risk for β-thalassemia can now be found antenatally using this technique, if the couple has given birth to a previous child, or, alternatively, the

TABLE 10-1
Restriction Endonucleases and Their Recognition Sites

RESTRICTION ENDONUCLEASE	SEQUENCE AT SITE OF RECOGNITION
Bam HI	5'-GGATCC-3' 3'-CCTAGG-5'
Eco RI	5'-GAATTC-3' 3'-CTTAAG-5'
Hind III	5'-AAGCTT-3' 3'-TTCGAA-5'
Hpa I	5'-GTTAAC-3' 3'-CAATTG-5'

Key:
A,C,G,T = Nucleotides
↓ = Site of cleavage

couple's parents are studied to confirm the linkage of variant genes to respective DNA markers (polymorphic restriction sites).[19] Families at risk should be studied as early in pregnancy as possible.

Clinical Management. The complexity and sophistication of the level of prenatal care required for patients with various forms of thalassemia covers a wide and varied spectrum. This can extend from providing little special attention for the heterozygous α-thalassemia-2 patient, pregnancy termination for patients with homozygous α-thalassemia, to the most extensive pregnancy support as is required of the rare but ever increasing number of pregnant patients with homozygous β-thalassemia.

ALPHA-THALASSEMIA

HOMOZYGOUS ALPHA-THALASSEMIA

A fetus that has the homozygous α-thalassemia defect will die in utero. In this condition all four genes are deleted and no alpha chains are produced. The fetus is incapable of synthesizing fetal hemoglobin or any of the adult hemoglobins. The predominate hemoglobin produced is Hb-Barts, which does not adequately release oxygen to tissues because of very strong oxygen affinity. This condition uniformally leads to high output cardiac failure, hydrops fetalis, and in utero fetal death. Homozygous α-thalassemia is reported to be associated with a higher inci-

dence of preeclampsia.[5] The need for antenatal diagnosis and the option of pregnancy termination becomes fundamental.

HEMOGLOBIN H DISEASE (HbH)

Hemoglobin H disease is the most severe form of α-thalassemia compatible with extra-uterine existence. It usually results from deletion of three, rather than four, genes.[20] In this condition both HbH and Hb-Barts precipitate in red cells to form inclusion bodies. On occasion, a moderately severe hemolytic anemia occurs as a result of removal of these cells by the reticuloendothelial system. When the anemia is progressive and threatens the integrity of the pregnancy, transfusion therapy becomes essential.

ALPHA-THALASSEMIA MINOR

In α-thalassemia minor (α-thalassemia-1) two genes are deleted and only a mild hypochromic, microcytic anemia results. Pregnancy outcome most often is good. The condition does have to be distinguished from iron deficiency anemia.

ALPHA-THALASSEMIA-2

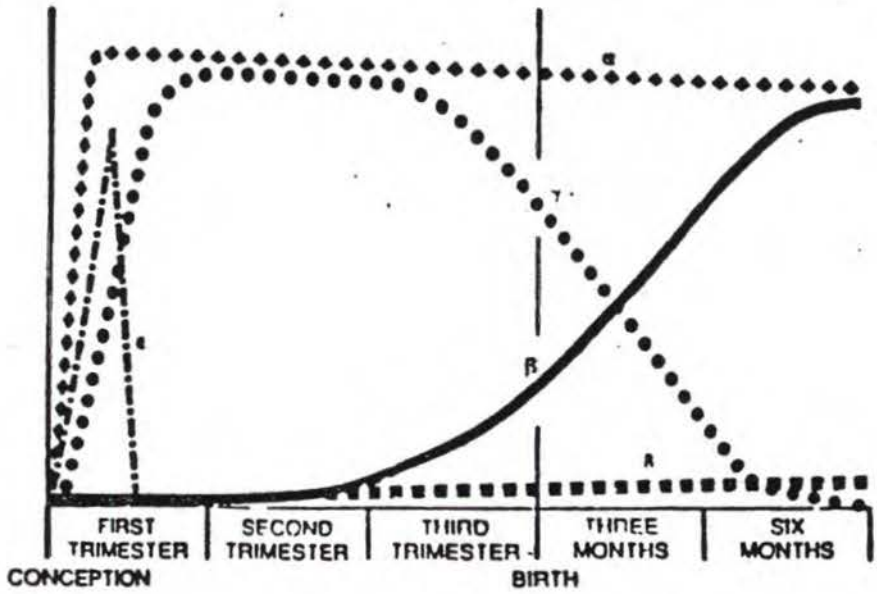
The silent carrier which results from a single gene deletion exists only in the laboratory and is clinically undetectable, requiring no special attention.

BETA-THALASSEMIA

BETA-THALASSEMIA MAJOR

Beta-thalassemia major (homozygous β-thalassemia) is not uniformly fatal in utero. As is depicted in Figure 10-2, the fetus requires primarily alpha chains and gamma chains to form HbF, and does not become highly dependent upon HbA until after birth. By age three months the infant with β-thalassemia major will become quite anemic with hepatomegaly. Blood transfusions can be required as often as every three to four weeks. Death is not uncommon by the third decade of life and usually results from myocardial hemosiderosis. Females surviving until puberty often have amenorrhea with resulting impaired fertility.[21] These patients rarely become pregnant.[22,23] Heart failure, susceptibility to infection, and a marginal ability to endure blood loss are all maternal hazards. Reproductive wastage is high and emanates from increased spontaneous abortion, stillbirths, and prematurity. Patient survival and the likelihood of a successful pregnancy are primarily dependent on multiple blood transfusions. Additional therapy includes appropriate use of splenectomy, folic acid administration and vigorous attention to intercurrent illness. With a multiple transfusion regimen, patient growth is enhanced, and cardiomegaly, bone malformation, and hepatosplenomegaly are reduced. Eighteen pregnant women with β-thalassemia major were followed through 51 pregnancies over a six year period.[21] Twenty-nine pregnancies were managed conservatively, and twenty-two pregnancies were augmented by liberal transfu-

FIGURE 10-2 Perinatal Globin Chain Synthesis



sions, with a maintenance of levels above 10 g/dl. Morbidity in the hypertransfusion patients was reduced, and total reproductive wastage dropped from 34.5% to 13.6%.[23] No circulatory overload occurred when patients were transfused in the sitting position, and a maximum of two units of packed red cells per week was not exceeded.

A consequence of any hypertransfusion program is the problem of iron overload. The iron chelating agent desferoxamine is employed to remove excess iron.[24-26]

Skeletal anomalies have occurred in fetuses of two animal species with dosages of desferoxamine that are slightly above those recommended for humans. Except in the face of acute iron intoxication, desferoxamine should not be administered during pregnancy, particularly in early pregnancy.

Splenectomy is recognized as the most useful therapeutic modality for patients with marked splenomegaly and a high transfusion requirement. The continued presence of an enlarging spleen compromises the patient by increasing the rate of red cell destruction. Ideally, splenectomy is best avoided during pregnancy. However, in the face of life threatening circumstances splenectomy can be safely performed.

Management of labor and delivery in the β-thalassemia major patient should be approached very much the same as with cardiac patients. Spontaneous labor is

favored, and cesarean section performed only for obstetrical indications. Because of anemia and a greater propensity for hemorrhage, conduction anesthesia should be used with caution. Regional infiltration anesthesia seems most appropriate.

BETA-THALASSEMIA MINOR

Patients with β thalassemia minor very often are unaware of their disorder. There can be a range of variation in the symptomatology of pregnancy, depending on whether or not the affected gene causes a reduction in beta chain production (β^+) or a complete absence of beta chain production (β_0). The clinical findings may range from an asymptomatic patient with microcytosis and increased HbA_2 (β^+ defect), to a patient with modest anemia, microcytosis with increased HbA_2, and mild splenomegaly (β_0 defect).

Most studies show no increase in adverse perinatal outcome among pregnant patients with β-thalassemia minor.[27,28,34] Folic acid is recommended although the literature is contradictory with respect to its value.[29] Pregnancy management for thalassemia trait patients is much the same as that for sickle cell trait patients.[30,31] The provision of excellent antenatal attention and care of these patients will result in prenatal outcome statistics matching that of the normal obstetrical population.

DOUBLY HETEROZYGOUS STATES

Doubly heterozygous S-β-thalassemia is associated with significant adverse perinatal outcome. Patients with HbD thalassemia or HbE thalassemia have a clinical course much like that of homozygous β-thalassemia and hence, rarely become pregnant.[12] Pregnancies are seen occasionally in three other types of doubly heterozygous thalassemia disorders--alpha/beta, delta/beta and HPFH (hereditary persistence of fetal hemoglobin). These doubly heterozygous states appear to have a mild prenatal course. From a practical standpoint, the key to management is antenatal diagnosis.

SUMMARY

The thalassemias are a genetically-determined group of disorders characterized by absent or reduced production of one or more alpha or beta globin chains. The evolving body of information concerning the genetic and molecular nature of this disease, and the ever increasing expertise in antenatal diagnosis has changed the approach to pregnancy management. Once there was little help to offer α- or β-thalassemia carriers; now we are able to provide a definitive answer regarding genetic risk. Couples can choose to avoid affected offspring without remaining childless. They can avoid the anxiety of awaiting the outcome of a genetically uncertain pregnancy status. For those rare pregnant patients with homozygous β-thalassemia, or one of the more serious doubly heterozygous conditions, much improvement has been made in providing good supportive management with use

of blood transfusions and splenectomy.

A new therapy for the thalassemias recently has been described that may be very beneficial.[33] The drug 5-Azacytidine, both in vitro and in vivo, has been shown to significantly increase gamma chain formation. Additional studies will be needed to estimate the overall risk/benefit ratio of this therapy before it can be widely applied.

EDITOR'S NOTE

The obstetrician needs to differentiate between β-thalassemia minor and iron deficiency (see Chapter 3). Prenatal diagnosis of almost all thalassemia syndromes can be performed. A recent review discusses the interaction of more severe thalassemia genes with sickle hemoglobin.[35]

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27. Sickle Cell Disease and Pregnancy: Management Controversies

Henry W. Foster, Jr.

After reading the case report the physician should:

1. understand the importance of a diagnostic work-up
2. understand the devastating effects of various types of sickle cell disease in pregnancy
3. appreciate the indication and the role of prophylactic blood transfusion.

Few conditions are associated with greater maternal morbidity and mortality and fetal wastage than is sickle cell disease in the pregnant patient. The current mortality is imprecise but is believed to be in the range of 1–2% and as recently as 1971 was reported at 10%.[1] Fetal wastage, including spontaneous abortion and perinatal deaths, approaches 40%. Because this is a genetically acquired incurable disease, treatment plans must for the time being be directed primarily toward alleviating symptoms. Therefore, management plans utilized in treating these patients must be empiric; the following case presentation serves as a backdrop from which to address several of the management controversies presented by this vexing condition.

CASE REPORT

A 16-year-old black adolescent, gravida 1, para 0, LMP December 12, 1985, was referred on March 3, 1986, by a neighboring county health department for obstetrical evaluation and care. The patient and her maternal grandmother, who accompanied her, stated that a diagnosis of sickle cell disease had been rendered in her first year of life. She had had repeated crises requiring hospitalization throughout her later life, occurring on average about three times a year. Her most recent crisis had occurred the preceding October. She stated that blood transfusions had been infrequent and that her crisis had been treated primarily with hydration, oxygen, analgesics, antibiotics, and rest. Menarche occurred at age 12 with a 28-day cycle of 4 days' duration. She had first become sexually active 6 months earlier and had not used contraception at any time during this period. The remainder of her history revealed she had no siblings. Her mother had died traumatically when she was an infant, and she had been reared by her maternal grandmother.

Physical examination revealed a shy, slightly built young woman, 62 in tall, weighing 117 pounds with a blood pressure of 90/40 and a pulse of 80 beats/min. Funduscopic exam was normal, and there were no leg ulcers. There was clinical enlargement of the uterus on pelvic examination, consistent with an 11-week intrauterine gestation, with ample pelvic dimensions. She expressed no interest in either pregnancy termination or antenatal diagnosis. Her hemoglobin level at that time was 8.2 g/dL and her hematocrit 23.9%. A report from the county health department revealed a hemoglobin electrophoresis that showed 88% hemoglobin S, 9% Hb F, and 3% Hb A_2. The patient was found to be stable, she was formally entered into our prenatal care system, multiple vitamins and folic acid supplementation were provided, and prenatal laboratory profiles were ordered, including a repeat hemoglobin electrophoresis. Hematologic evaluation included the serum ferritin level and urine cultures, and she was advised that elective hospitalization would be planned for approximately 24 weeks' gestation (or sooner if indicated) for the primary purpose of conducting prophylactic partial exchange transfusion (PPET). Until that time the patient was advised to be seen as an outpatient every 2 weeks.

The patient was hospitalized on June 6, 1986, and discharged on June 7, 1986. During this visit she received four units of washed buffy-coat-poor packed red blood cells via PPET. During

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Question 1: What for obstetrical sickle cell gene

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the remainder of her pregnancy she was hospitalized on three subsequent occasions: (1) August 4–8, 1986, for acute pain crisis, for which she received three PPETs and supportive therapy; (2) September 15–19, 1986, for a urinary tract infection, treated with ampicillin; and (3) September 24–October 3, 1986, again in crisis, treated with a single PPET. Vaginal delivery was effected during this last hospitalization, utilizing Pitocin induction under epidural anesthesia. A female infant weighing 6 pounds, 6 ounces, with 1 and 5 minute Apgars of 8 and 9 was delivered over an intact perineum. The patient did not nurse her infant. She was discharged home 3 days later to be seen in 2 weeks for contraceptive advice, and she was to continue using her prenatal vitamins and folic acid 2 mg per day.

Question 1: What screening test should be used for obstetrical populations at risk for the sickle cell gene?

There are two basic types of approaches to screening: (1) solubility testing initially, followed when necessary with hemoglobin electrophoresis, and (2) hemoglobin electrophoresis followed by solubility testing and/or citrate agar gel tests, if necessary. Each approach has its advantages and disadvantages. There are several solubility tests (or so-called "sickle preps") that are quite satisfactory as screening devices. These tests utilize sodium metabisulfite to produce sickling of affected erythrocytes by reducing oxygen tension. The most significant advantage of this approach to screening, perhaps, is the inexpensive cost of this procedure. Additionally, it requires only a single drop of blood and hence can be obtained from a finger prick. Also, the results are known within a matter of minutes. There are, however, disadvantages that, in my judgment, outweigh the advantages.

Sodium metabisulfite is not adequate for the detection of Hb C, except for C-Harlem, which comprises only about 15% of Hb C (Hb C has a prevalence of 1 in 60 black Americans); therefore, when using the "sickle prep" the majority of women who possess Hb C, which is 85%, will not be detected. It is quite plausible that a woman's mate could carry the sickle trait (Hb AS), given its prevalence of 1 in 12 blacks. The situation has now been created for this couple to produce a child that inherits Hb SC disease—a possibility not expected since the mother was "screened." Further, this solubility test, when positive, does not distinguish sickle cell trait from sickle cell disease. This determination must be made by hemoglobin electrophoresis. Also, the false-positive rate is relatively high with this test, but this is acceptable, unlike a high false-negative rate, which would be unacceptable.

The cost of performing hemoglobin electrophoresis as a method for screening has been viewed as a disadvantage; however, the cost of this test should not be considered prohibitive if cellulose acetate is used. Further, this screening approach affords the opportunity to identify the presence of thalassemia by detecting Hb A_2 in a quantity greater than 3.5%. However, this value may be misleading in the presence of iron deficiency and must be repeated when the iron deficiency has been corrected.

Question 2: Does sickle cell trait (Hb AS) increase maternal or perinatal mortality?

There are no documented studies showing any increase in either maternal or perinatal mortality in patients who carry the sickle cell trait, i.e., who are heterozygous (Hb AS). There are, however, some patient management issues that are different from those in the general population that warrant special consideration. Patients with sickle cell trait require competent and compassionate genetic counseling because they are at risk for producing offspring with sickle cell disease (Hb SS). It is important for these trait patients to know that their genetic condition most likely occurred as a spontaneous mutation in response to the malaria parasite *Plasmodium falciparum*. Such an explanation provides patients a rationale for why their condition exists, which helps decrease the stigmatization they often feel. Audiovisual material is useful in explaining the genetic implications of the disease. Genotype charts displaying percentage inheritance odds are particularly useful. The most frequent risk is the trait-by-trait (Hb AS/AS) mating; it carries a 25% chance of producing a child with the sickle cell disease (Hb SS) and a 50% chance of one with the trait (Hb AS). When either parent has the disease (Hb SS), there is no chance for any offspring to escape the inheritance of S hemo-

globin, irrespective of the genotype of the other parent.

Those pregnant sickle cell trait patients at risk for producing an offspring with sickle cell disease (Hb SS) now have the option of antenatal diagnosis using amniocentesis or chorionic villus sampling for restriction enzyme analysis of fetal genomic DNA. This ability to ascertain the fetal hemoglobin status in utero extends our capacity to provide genetic counseling. Such capability affords the option of pregnancy termination, as is available with other genetically propagated diseases such as Down syndrome, Tay-Sachs, neural tube defects, etc.

Pregnant patients with sickle cell trait have increased morbidity as it relates to the urinary tract. Asymptomatic bacteriuria is reported in 25% of these patients (8% in the general obstetric population), and pyelonephritis in 7% (2% in the general obstetric population). Additionally, these patients have gross hematuria, and over time patients with trait may develop hyposthenuria—the inability to concentrate urine. As red blood cells flow from the kidney cortex to the medulla, there is a progressive increase in osmolarity (up to 1200 mOsm) as the medulla is reached, resulting in stasis, sickling, ischemia, and, over time, permanent structural damage. Since approximately 14% of the nephron population is juxtamedullary, hyposthenuria can become a clinical manifestation. Both sickle cell trait and sickle cell disease patients should have urine cultures and sensitivity studies done in each trimester. Positive cultures should be treated with appropriate antibiotics for 3 weeks or until negative.

There has been one retrospective study that suggests an increased incidence of premature rupture of membranes in patients with sickle cell trait. The findings were not statistically significant, and no other report of this phenomenon has appeared.

Question 3: Should PPET be used in managing patients with sickle cell disease?

Probably the most controversial issue of all for these patients is that of PPET. The risk-benefit ratio is by no means certain. The many aspects raised in this controversy can only be answered through a randomized multicenter collaborative study; however, previous such attempts have been unsuccessful because of the wide empiric use of PPET in many centers.

The first published suggestion that exchange transfusion might be used for prevention as well as treatment of sickle cell disease appeared in 1963. Several physicians interested in this topic have employed PPET rather widely over the past 12 years. Perhaps the most important lesson learned during this period is that this is not an all-or-none question. There seems to be emerging a subgroup of hemoglobinopathy patients who are more likely candidates for this application than are others. Determinants of those comprising this group include such entities as (1) the historic pattern of the disease (e.g., frequency and severity of crisis), (2) associated complications (e.g., peripheral ulcers, visual disturbances, kidney function, and other infections), (3) the type of hemoglobinopathy (i.e., homozygous [Hb SS], doubly heterozygous [Hb SC], and Hb S β^{o}-Thal or Hb S β^{+}-Thal), and (4) the protective effect of Hb F. The risk-benefit ratio will be best applied if these items are critically assessed in choosing candidates for PPET. The possible advantages and disadvantages are listed in Table 27-1. In terms of benefit the replacement of Hb S with Hb A produces almost immediate clinical improvement. Although not yet statistically significant, some reports have shown an increase in average birth weight of 200 g for infants born to mothers who have sickle cell disease who received PPET. The patient described in this case study had two pain crises (vaso-occlusive) during her pregnancy. Each was treated with PPET, and it is felt that both the severity and the duration of her crises were lessened with this intervention. And, of course, in this case her infar
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Table 27-1 Prophylactic Partial Exchange Transfusion

Possible Advantages	*Possible Disadvantages*
Reduced Hb S cells	Incompatibility
Increased Hb A cells	Transfusion reaction
Suppressed Hb S	Hepatitis
prophylaxis	isoimmunization
erythropoiesis	Volume overload
Increased oxygenation	Febrile reaction
Increased sense of well-being	Hemochromatosis
Improved perinatal	Premature labor
outcome	Psychologic
Reduced infections	dependence
Reduced crises	HIV transmission

R=94%

this case her infant's birth weight was certainly adequate.

The possible disadvantages of this therapy are real. Perhaps the greatest concern is the large number of red blood cells used in this procedure, with the possibility of isoimmunization. Patients have become severely sensitized and virtually incapable of being compatibly cross-matched. The risk of transmitting human immunodeficiency virus (HIV) remains a clear concern despite recent advances in blood banking techniques.

The potential problem of iron overload seems more theoretical than real. With PPET iron is removed, albeit a smaller aliquot than that which is replaced. Beyond this, women are relatively protected by their periodic menstrual blood loss, iron loss to the fetus during pregnancy, and the blood loss that accompanies parturition.

The question of volume overload can be greatly minimized by transfusing patients in the sitting position at recommended rates of flow, or it can be virtually eliminated by employing automated erythrocytopheresis. The latter technique uses a cell separator to remove the patient's blood via phlebotomy and subject it to differential centrifugation, separating the patient's plasma into its various components (clotting factors, red blood cells, white blood cells, etc.). Only the patient's Hb S-containing red blood cells are discarded. Transfused Hb A-containing cells are returned to the patient's circulation along with her other components not discarded, while maintaining a balanced-closed hemodynamic system at all times, virtually eliminating any likelihood of volume overload.

Question 4: What fertility control method is best for sickle cell disease patients?

Choosing the best method of contraception for these patients is at best an empiric exercise. The controversies are several. The estrogen/progestin oral contraceptives present relative contraindications—at least theoretically—because their estrogen component increases blood coagulability, thus lowering the threshold for crises. Gallbladder disease, which is a contraindication to pill use, is also seen more frequently in patients with sickle cell disease. However, these factors notwithstanding, pill use by these patients undoubtedly presents a smaller relative risk than does pregnancy. Progestin-only contraceptives such as the minipill and long-acting intramuscular hydroxyprogesterone are good choices. At our institution we offer the long-acting intramuscular hydroxyprogesterone, 150 mg every 3 months. It is realized that this medication is not approved by the FDA for contraceptive use in this country; however, written informed consent to this effect is obtained prior to its usage. To date, no patient has refused, and none has become pregnant.

Most practitioners feel that use of the IUD in these patients is contraindicated. The two complications that are of greatest concern are infection and excessive vaginal bleeding. It appears that many patients with sickle cell disease are immunocompromised; hence, their immune systems should not have to contend with a chronic foreign object in the uterine cavity.

Barrier contraception obviously has few side effects except, of course, pregnancy, which in my judgment makes its use of questionable value.

Many sickle cell disease patients, having once achieved a successful pregnancy outcome, opt for permanent sterilization. Laparoscopic sterilization is not recommended for them; this procedure compromises pulmonary aeration because of the relatively high fixed position of the diaphragm. Ninety percent of laparoscopic procedures conducted in this country use carbon dioxide to establish the pneumoperitoneum, which promotes hypercarbia. The elevated P_{CO_2} and lowered pH have been shown to be the result of CO_2 absorption from the peritoneal surface and not necessarily from improper ventilation during anesthesia. As an alternative the interval or postpartum minilap sterilization procedure, ideally using local anesthesia, is recommended.

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CASE REPORT

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FAMILY PLANNING AND THE BLACK COMMUNITY

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The concept that every women in the childbearing age should have the right to maintain control over her own fertility is, I believe, an accepted principle in 1975. However, for patients to be able to recognize and exercise this right, there is the need to conduct a massive educational effort: (a) to have health personnel include family planning as a part of the comprehensive health services they provide; (b) to educate the public (the patient) to appreciate good health and how to maintain it. The assumption is that the patient (the woman in this instance), once emancipated from her own ignorance is likely to take over control of her own fertility.

In structuring family planning services, there are some basic principles that must be adopted and adhered to very strictly. Briefly, they are:

1. Voluntary family planning is a significant health measure. Family planning information must be provided in such a way whereby anonymity is maintained.
2. Family planning services must be delivered humanly and in physical surroundings that are adequate.
3. Male participation in family planning must be sought.
4. Family planning settings can provide many noncontraceptive services for patients.
5. Population concerns are inappropriate for family planning programs.
6. Abortions are safer when performed in early pregnancy.

Any family planning services which do not embrace all of these principles are deficient and potentially harmful especially for the ghetto populace.

The potential benefits to be derived by the provision of adequately structured and properly delivered family planning services are well established. In addition to the achievement of optimal family size by those obtaining voluntary family planning services, there will follow the other expected benefit of family planning—the improvement of health. Thus family planning means better health and I am in accord with the broadened definition of health as adopted by the World Health Organization (WHO):

"A state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity."

There obviously is a need to lower infant mortality and decrease maternal mortality and morbidity. This need can be addressed by better spac-

ing of wanted pregnancies and the avoidance of unwanted pregnancies. Particular attention must be paid to women in high risk groups which so often characterize the inner city childbearing population.

Some maternal mortality findings relating to high risk groups are of particular note, e.g., maternal mortality rates for patients under 20 years of age are about one-third higher than those for patients aged 20-24. Toxemia and abortion related deaths are 2 times higher for women under 20. Other studies from the population council have shown that the newborn of a teenage mother has a 30% increased risk of dying prior to its first birthday. Premature births for women under 20 is 34% higher than for mothers in the 20-24 age range. Furthermore, a very large proportion of women seeking abortion are not using birth control measures. Again, this is magnified in the teenager. For older mothers, those over 40, the infant mortality rises sharply as it does in mothers after the fifth pregnancy.

Based on these facts, how then could there be anything other than overwhelming reception of family planning services by everyone? How could there be resistance to these services? The answers to these questions, of course, are multiphasic, complex and like so many complex issues, are deeply embodied in the sociocultural fabric of the environment.

When describing barriers to the health services, of which we speak, sociologists often use the terms, "attitudinal" and "organizational." Generally, attitudinal barriers prevent the individual in need from becoming motivated to seek the available service, whereas organizational barriers prevent the motivated individual from utilizing the services that are desired. Most often a combination of both barriers is at work when needs go unmet and obviously the problems of family planning are increased when the setting is an urban inner city.

Ghetto life is in general characterized by a relatively unsophisticated culture which has resulted in great part from the economic and political isolation that has characterized this group. Because of isolation, there is a strong orientation towards fatalism which helps explain resistance to any alteration in reproduction and the reproductive process. This factor creates a significant barrier to family planning motivation in this segment of our population. Consequently, successful family planning programs will remain difficult to achieve as long as attitudinal barriers exist.

Organizational barriers confronting the motivated ghetto patient seeking family planning services are often overwhelming. However, unlike attitudinal barriers, organizational barriers are more tangible and thus more readily identifiable. In this regard, poverty constitutes an awesome barrier and is inseparable from all others. Additional organizational barriers are maldistribution of health personnel, problems of transportation, communications and deficient physical facilities. A complex interface of the attitudinal barrier involves collectively the ghetto patient and his or her physician both of whom often are Black.

In recent years there has been an outcry by various groups that the

intent of family planning is Black genocide and that the ultimate effect will be Black genocide. These apprehensions are quite understandable and on occasion are well founded. In June of 1970, the first National Congress on Optimal Population and Environment convened in Chicago, Illinois. Invited participants included about 45 Blacks representing such Black institutions as the Urban League, Tuskegee Institute, and Howard University. Shortly after the Congress convened, this group of individuals formed a Black Caucus on an ad hoc basis. After considering the major problems being discussed and the solutions proposed, the ad hoc group observed that the Congress in its overall planning had been derelict by failing to obtain significant Black input to reflect Black interests and concluded that the purpose of the Conference was to use those delegates invited as pawns to legitimize a preconceived plan of vicious extermination. If these views seem irrational, it is to some degree understandable. There is no doubt that there are those in this country who indeed would be delighted if Blacks became extinct.

However, it is my firm conviction that the majority of this country's health providers have never in a conscious manner planned a program of genocide for Black people and indeed are motivated by a sincere desire to be beneficial. What has occurred, however, is that many well-intentioned family planners and family planning programs have been set up for large segments of the Black population, without due consideration of many significant factors to which they can relate. Without consideration of such factors, the end results of far-reaching family planning programs can have very disasterous consequences for Black people. Nonetheless, because of the inherent health benefits that can be derived from properly structured family planning programs they have my support as a Black physician, but this support is of necessity conditional. Accordingly, I consider it axiomatic that the following three basic conditions be met prior to my lending support to any family planning program:

1. All family planning programs must be completely voluntary and that no coercive family planning programs be allowed to become part of a national or local legislative policy.
2. Comprehensive health care must be a viable component of any family planning program including the capability of infertility diagnosis and therapy.
3. All family planning programs for Blacks must include effective Blacks at every substantive policy making and administrative level.

It is absolutely essential that these three prior conditions be met and to do otherwise is totally unacceptable.

All too often, family planning services being provided are not voluntary. Consumers many times are unfairly cajoled by not only physicians but almost any member of the family planning team. Patients are belittled and berated often openly if they refuse services or even show reluctance. Far more frightening than this, however, is the legalization of coercive ster-

lization practices. Social welfare legislation in this form removes the right of a woman receiving welfare benefits to have children.

Additionally, other areas of health care must be given as high a priority as family planning. I believe that the case for the positive aspects of family planning has been established, but just how far these positive aspects go, in the face of deficient comprehensive health care, cannot be answered. In fact, I pose the following questions: Is it wise to attempt to approach a national zero population growth in a group where the infant deaths are twice that of the national average? Might not a higher birth rate in such a group at some time serve as a necessary protective mechanism in that group where the life expectancy is significantly less than that of the national average? All too often, family planning is given a disproportionately higher priority than are other essential areas of health care. I am suspect when I see extensive family planning services being provided in a locale where, if, the same patients become pregnant or require other health services, none are available.

Most family planning programs are predicated and structured on the erroneous assumption of a common national life style. Because of the differences in life style characteristics of this country's heterogenic make-up, it becomes mandatory to include Blacks at meaningful policy making and administrative levels when structuring and providing family planning services for Black people. To those who are deprived socially and economically the procreative processes often become the only fulfilling life experience available. To curtail or remove this avenue of expression is often tantamount to taking away the only need for existence itself. Therefore, and in conclusion, it is fundamental for the providers of family planning services to have the recommended insights. Every human being has a need to feel creative—it is a drive not easily relinquished. The challenge to us as professionals and as a nation therefore is to continue to make available to everyone many avenues of expression for this creative need.

LEGISLATIVE FORUM STATEMENT ON TEENAGE PREGNANCY

Representative Waxman, and Committee Members, my name is Henry W. Foster, and I am chairman of the Department of Obstetrics and Gynecology at Meharry Medical College in Nashville, Tennessee and I also serve as director of the Robert Wood Johnson Foundation's Program to Consolidate Health Services for High-Risk Young People which has 18 projects located in 20 cities in this country. I very much appreciate the opportunity to make this statement before your Committee on behalf of the National Medical Association.

The problem of early child bearing in this nation is truly one of epidemic proportion; we anticipate 1,200,000 such pregnancies this year. Ingloriously, the United States leads all western nations in this category. The problem is even greater for minorities and the poor. Recent data from the National Center for Health Statistics estimate 74.2 births per 1,000 unmarried black females age 15 through 17. For white females in this category the figure is 11.8 births; however, over the past 10 years the birth rate in this category for blacks has decreased by the 4.7% while it has increased by an alarming 36.4 for whites. Without question, early child bearing is a significant problem for our nation.

The causes of such outcomes understandably are multiple and complex. For so many youngsters, teenage

childbearing is a societal symptom and emanates primarily from deprivation. This deprivation is characterized by racism, urban decay, family dissolution, welfare policies, illiteracy and a variety of other factors. The problem of teenage childbearing will not go away until we begin to effectively address these quality of life issues.

Unwanted pregnancies must be prevented. Prevention can be viewed from three (3) perspectives--programs that enhance knowledge, programs that provide access to contraception and interventions that improve marketable skills. Earlier this year, the National Urban League and the National Association for the Advancement of Colored People convened an invitational meeting of national black membership organizations to address issues attendant to black families. I was asked by Dr. Lucius Earles, President of the National Medical Association to represent our organization in that forum. I participated in the concurrent work session that dealt with single parent families and adolescent pregnancy. Our group developed the following eight recommendations, which I believe will be useful to your Committee:

1. Provision of incentives to teenagers not to get pregnant and not to impregnate, e.g. the provision of such rewards as scholarships, jobs and job training opportunities.

2. Structuring skills development programs in prime relevant jobs with the promise of upward mobility.

3. Provision of sexuality education provided by trained peers, trained adults, trained clergy to occur at home, at school and at church with equal emphasis on each sector.

4. Communicating the values of deferred gratification through development of ceremonies of "rites of passage" in order that our youth can learn there are rewards at all developmental levels.

5. Sponsoring positivity focus youth groups by churches, schools, sororities, fraternities and other black institutionsand other organizations.

6. Pooling funds and sharing resources to counter act negative group persuasion through programs described as frank and personal integrity, family loyality, and personal pride.

7. Addressing the mass media by local and national organizations, demanding positive portrayal of ethnic and racial images. Demand public service programs and announcements designed to improve the images of blacks and their families.

8. Emphasis on restructuring the labor market and directing government funding priorities away from defense and towards job training and full employment to metigate against the possibility that generations of black youths might never

To help implement these and other appropriate recommendations, I say to this Committee it is axiomatic that funding be increased in the four major federal entitlement programs that promote reproductive knowledge and provide contraceptive access i.e. Title X, of the Public Health Service Act and Titles V (Maternal and Child Health), XIX (Medicaid), and XX (Social Services) of the Social Security Act. Additionally, this Committee needs to support appropriate legislation that

will enhance job and academic opportunities particularly for black teenagers, thus leading to better marketable skills. We must provide other avenues of creative expression for our young people rather than teenage childbearing.

Again, I wish to thank this Committee for affording me the opportunity to make this brief statement on behalf of the National Medical Association. I am most hopeful that tangible benefits will follows.

Respectfully submitted

Henry W. Foster, Jr., M.D.

July 20, 1984

CONTRACEPTIVE EFFECTS OF BREASTFEEDING AND EFFECTS OF CONTRACEPTION ON BREASTFEEDING

Henry W. Foster, Jr., M.D.

I am especially honored to have been invited to serve as your banquet speaker tonight. It's good to be with friends. I extend my genuine congratulations to Tuskegee's Department of Home Economics, conference committee members and particularly to Dr. Rankins, whose role as chairperson has been crucial in assuring the success of this 40th Annual Food and Nutrition Institute.

Additionally, my congratulations are extended to all of you here who continue to work so assiduously to address the myriad of difficult health and nutrition needs which characterize the population you serve. I cannot help but recall some of the pioneers who established this legacy who have passed away—such as John Kenny, Sr., John Chenault, Louise Trigg, Horace Dwiggins, Eugene Dibble, Tom Campbell, and Joseph Mitchell.

My anticipation of tonight's banquet was heightened last month when I received a preliminary conference program and saw that so many of the participants were colleagues, friends and, in some cases, former patients. You continue to labor in the vineyards Fred Gray, George Cooper, Eleanor Hines, Beatrice Phillips, Lillie Robinson-Mays, Robert K. Williams, Ralphenia Pace, Walter Sapp, Elaine Thomas, and Thelma Walker-Brown. From 1964 through 1973, when I resided in Tuskegee, 17,000 births occurred at John Andrew Hospital and during that time, I worked in some capacity with each of you, but none more closely than with Thelma Walker-Brown. Although Louise Trigg and I had the major responsibility for writing the Maternity and Infant Care Grant that benefited so many of those patients, it was indeed Thelma Walker-Brown, as senior nurse coordinator for that project,

who made this grant work. I will always be grateful for her energy, intelligence and wisdom.

Enough for reminiscences.

In life, there is no greater advantage than a good beginning nor a greater burden than one that is compromised. Thus, the theme you have chosen for this year's Food and Nutrition Institute is most appropriate. Setting Breastfeeding as a Norm for Low Income Families clearly will help achieve better health care outcome. However, I hasten to add that one's inability to control their fertility also creates a staggering burden. My task this evening, therefore, is to examine briefly, how these two fundamental needs, which on occasion are at cross purposes, can best be reconciled. There is a framework in which this can be accomplished. In order to elucidate this answer, let us examine briefly (1) general benefits of breastfeeding, (2) the need for contraception, (3) the contraceptive effect of nursing, and (4) the application of contraceptive modalities to the nursing mother.

On June 11 and 12 of last year, I participated in the Surgeon General's Workshop on Breastfeeding and Human Lactation held at the University of Rochester Medical Center in New York. At that gathering, the Surgeon General, Dr. C. Everett Koop, sat a clear and measurable goal for the nation, "...that by the year 1990, the proportion of women who breastfeed their babies should be increased to 75 percent at hospital discharge and 35 percent at six months of age." He went on to note that the last decade has seen a steady increase in breastfeeding primarily in middle and upper income educated white women. The need was recognized to identify and reduce barriers that interfere with breastfeeding, especially in those population groups with low prevalence of breastfeeding, i.e., minorities.

low income and less educated women. It is particularly ironic that 35 years ago these findings were just the opposite.

The benefits of breastfeeding to mother and infant are significant. Milk produced by the mother is the ideal food for her infant. Breastfed infants receive immunological benefits that can be derived in no other way. Human breast milk contains secretory IgA antibodies against Escherichia coli, thus making them less prone to enteric infections than their bottlefed counterparts. Also, it is likely that better control of caloric intake by these infants results from nursing.

Numerous benefits occur to the mother which are a consequence of breastfeeding. There are the psychological benefits of enhanced mother-child bonding with its potential for improving parenting. More rapid uterine involution occurs resulting in decreased postpartum blood loss and less susceptibility to infection. It has been shown that breastfeeding results in the use of the mother's stored fat as her major energy source thus leading to more rapid and efficient postpartum weight loss. There is also the potential for monetary benefit from lowered food costs for the infant. This can be pivotal for a low income family.

The capacity to control one's own reproductive fate is an absolute requisite to successfully compete in today's society. Uncontrolled reproduction either for the individual or a nation is a formula for failure. High birth rates in times past were protective in the face of extremely high infant death rates. This is no longer the case, as infant deaths have declined sharply. There are numerous nations in the world today that continue to slide deeper into poverty inspite of a steadily increasing annual GNP--their excess population growth has simple out stripped their productivity. Just imagine, even with the extent contraception is practiced

today, 240,000 new individuals are added to this planet Earth with the passage of each 24 hours. At the time of my birth, there were just over 2 billion people on earth. This figure has already more than doubled in my life time being estimated currently at 4.8 billion and projected to reach 6.3 billion people by the year 2000.

Isaac Asimov has noted that no modern nation has ever made substantial economic progress until its women were able to control their reproduction. He so aptly points out that once women can control their reproduction, this frees them to enter the work force, hence, the nation's brain power pool doubles. With this backdrop, it should be apparent that both breastfeeding and contraception are beneficial and should be supported.

Much confusion exists in the minds of many as to the contraceptive effect, if any, of breastfeeding. Confusion exists because a yes or no answer can be correct depending upon how the inquiry is phrased. Let me provide an example—question, Is there contraceptive benefit for women who breastfeed? The answer is Yes. Question, Can breastfeeding be relied upon as an effective contraceptive measure? The answer is No. Breastfeeding delays, but does not prevent the return of postpartum fertility. Demographically, this translates into a definite but variable contraceptive effect. However, for individual couples, it is not reliable.

The data vary widely as to the contraceptive benefits of lactation. The reasons for the variation are multiple. It is totally misleading and inappropriate to extrapolate data from one cultural group and apply it to another—especially when they are highly dissimilar. Unfortunately, this has often been done and, in great part, explains much of the reporting inconsistency. Studies that have yielded the best contraceptive effects from breastfeeding have come from cultures where intercourse is routinely

delayed up to one year after birth. Further, it is most important to understand that for breastfeeding to have its maximum contraceptive effect, it must be provided on-demand without bottle supplementation—an exceedingly difficult task in our western culture. Demand feeding keeps serum prolactin levels elevated which secondarily inhibits luteinizing hormone that is needed to cause ovulation. Even in patients who breastfeed on-demand, eventually breakthrough ovulation will occur and 80 percent of the time it happens prior to the first postpartum menstrual period. This attests further to the need for an effective contraceptive measure while nursing. Once menustration has returned the likelihood of pregnancy is equal in both nursing and nonnursing women.

At this point, I now believe it fair to reach the three following conclusions: (1) breastfeeding is beneficial to both mother and infant, (2) contraception is desirable for the individual and as a national policy, and (3) breastfeeding cannot be relied upon as an effective contraceptive modality. Given these conclusions, let us now turn to the subject of choosing a contraceptive for the breastfeeding mother.

The perfect contraceptive can be defined as 100 percent effective all of the time, free of complications, not interfering with the spontaneity of sex, with its effects being immediately reversible when conception is sought and its use the shared responsibility of both partners. Now obviously, this is an ideal, not likely to be attained. There are, however, methods available each having its own advantages and disadvantages. Temporary contraceptive measures commonly can be categorized as steriods (the pill), IUD (intrauterine), and barrier methods which include diaphragms, condoms, jells, foams and the recently developed sponge. With any contraceptive, the major considerations are effectiveness and safety which tend to act

reciprocally, i.e. as effectiveness increases, safety decreases. Convenience is also a very significant consideration.

In order to understand the relative effectiveness of various contraceptive modalities, a brief explanation of the pregnancy rate is in order. By definition, the pregnancy rate is defined as the number of pregnancies per 100 women years. I realize this definition makes little sense. But in fact, it only refers to the number of annual pregnancies that occur per 100 women. The annual pregnancy rate for noncontracepting women in this country is 80. This means that in a 12-month period, 80 of these 100 women will have become pregnant. You now have a standard against which to measure the effectiveness of the various forms of contraception in use today.

The first and least effective is the timing or rhythm method. This form of contraception has a pregnancy rate of approximately 40, which is unacceptably high. Further, its use is predicted on being able to anticipate when ovulation will occur, which basically cannot be done in lactating women.

The barrier methods are associated with a pregnancy rate of about 15, which is a significant improvement over the pregnancy rate of 80 in noncontracepting women and that of 40 with the rhythm method. All barrier methods can be safely used in lactating women and aside from their relatively high pregnancy rate, have no known adverse side effects. Additionally, all except the diaphragm and cervical cap can be used anytime in the postpartum period. The diaphragm and cervical cap cannot be properly fitted however, until after six weeks postpartum when the pelvic organs have properly involuted.

The pregnancy rate with the IUD is approximately 4 per year, and it

does not interfere with breastfeeding. However, as with the diaphragm and cervical cap, they cannot be properly fitted prior to the six week postpartum examination. Increased uterine cramping has been reported with IUD use in nursing patients, but this is usually transient and not a major deterent to nursing.

As you have probably surmised, the pill, which is by far the most effective contraceptive having a pregnancy rate of 1 per 100 women per year, is associated with the most controversy particularly as it relates to breastfeeding.

When one examines the literature regarding the relationship of oral steroid contracepting to breastfeeding, the data are confusing. This ambiguity exists primarily because earlier studies were done using very large steroid doses. Secondly, the parameters being studied have never been standardized.

With respect to dosage, most early studies revealed that the estrogen component of the birth control pill interfered with lactation onset, milk volume, and milk composition. However, the first generation birth control pills contained 100 to 150 mcg of its estrogen component. The current generation of birth control pills average only 30 to 35 micrograms of estrogen. But this notwithstanding, several researchers have found that even these relatively low dose estrogen pills can negatively affect milk supply especially if the pills are begun in the immediate postpartum period.

It will be difficult to assess the impact of hormonal contraception on breastfeeding until concensus is reached as to which aspects of the problem should be measured, e.g., the quantity of milk, its composition, the length of lactation, weight gain in the infant, etc. Further, once a standard of comparison is chosen, the question of matched controls and

various birth control pill hormone formulations must be determined. Until this occurs, a definitive statement as to the effect of birth control pills on lactation performance will remain conjecture.

At this point, I will not make an absolute statement with respect to birth control pill usage in the lactating patient. I can advise that it is not my first choice, generally, I favor the IUD. The low dose birth control pills clearly are very effective in their contraceptive action, and on occasion, they can be recommended for the breastfeeding patient. However, they should be initiated only after breastfeeding has been well established. The progestin-only or mini pills have also been studied and they too have been found to decrease lactation--again, especially when started in the immediate postpartum period.

There seem to be no major adverse effects on the fetuses of nursing mothers who do utilize birth control pills. There is reported in the early literature a single case of gynecomastia developing in the male infant. This occurred on the 100 microgram dose estrogen pill. Also, it has been shown that the amount of estrogen that reaches the nursing infant whose mothers are taking the low dose estrogen pill is actually less than that which would reach them if the mothers were ovulating and nursing.

As a final note, physicians are strongly urged to consider not using heavy sedation and general anesthesia for postpartum tubal sterilization surgery in prospective nursing mothers. The sedation can have a compounding effect; it can inhibit milk letdown in the mother and the sedative agents can pass via the milk to the infant reducing its sucking capacity. This reinforces a destructive cycle adversely affecting the whole nursing process.

In closing, it is my observation that breastfeeding in today's

[redacted]

western technological culture is not a simple easy task that just comes "naturally." Further, when the need for contraception is superimposed, the difficulties of each chore are compounded. These patients need encouragement, education, and a health care support system characterized by caring and knowledgeable providers. All of you as a team here at Tuskegee University possess these attributes. It is, therefore, most appropriate and timely that the promotion of breastfeeding has been chosen as your Institute's theme this year. I very much appreciate your allowing me to be a part of this laudible effort.

Thank you very much!