interactive clinical computer systems, such as that piloted by Weed more than 20 years ago,¹⁵ may yet come of age.

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Audit of compliance with antenatal protocols

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Abstract

Objective—To assess the implementation of action protocols dictated by antenatal risk factors noted at the initial (booking) antenatal visit.

Design—Retrospective study of 2000 women delivered between 1 March 1990 and 29 March 1991.

Setting—Maternity department of a district general hospital supporting a multiethnic population in inner London.

Main outcome measures—Comparison of clinical actions performed against those dictated by the department's protocols. Analysis according to clinical importance, gestation at booking, maternal age, parity, birth order, ethnic origin, and certainty of gestational age.

Results—Interobserver agreement between the two auditors was good (κ statistic for risk factors detected, 0.78; for actions generated, 0.80). Of the 15658 actions dictated by department protocols, 3673 (23.5%) were actually performed by the clinicians. The 63 combinations of risk factors and actions believed by consultants to be of particular clinical importance had an action rate of 28.3% compared with 18.6% for those considered less important ($p < 0.001$). Mothers who first visited the hospital antenatal clinic at or before 24 weeks' gestation had 25.2% of relevant protocols fulfilled ($p < 0.001$). Compliance was significantly improved in women aged 36 or over (32.4%), black women (24.9%), and cases of uncertain gestation (24.5%). Parity and birth order were not associated with an altered action rate. Ethnic origin deemed as "other" (than white, black, Asian, or oriental) or "unknown" was associated with poor compliance (19.3%).

Conclusions—Compliance to a set of agreed protocols was poor even though a computer system was available and a protocol manual had been distributed. Protocols were more likely to be implemented in women who booked early and in some groups of women deemed at high risk including older mothers, black women, and those denoted as having uncertain gestational age.

Introduction

The process of antenatal care and the management of pregnancy is determined largely by the detection of

risk factors at the first antenatal attendance (booking visit). The Sighthill scheme promoted a high standard of antenatal care by ensuring that each pregnant woman was formally assessed: features of the pregnancy were noted against a checklist of risk factors; a continuing plan of management using specialist and community services, based on locally agreed protocols, would then be organised and instituted with the help of risk cards.¹ A similar programme, developed at the Homerton Hospital, used a computer system to help detect obstetric risk factors.² About half of the pregnant women attending the hospital have their booking history collected with this clinical information system; the computer generates a printed antenatal report, in which a list of relevant risk factors appears on the first page. In 1986 a detailed set of protocols for antenatal care was devised. These protocols defined 46 risk factors that could be identified at the booking visit, together with appropriate actions to be followed should a risk factor be found.

Two previous studies that analysed medical management according to recorded antenatal information concentrated on the recognition of risk factors at the booking visit rather than the adequacy of the medical response.^{3,4} In neither study were protocols for specific actions in response to specific risk factors stated to be clearly established before antenatal care was given to the mothers. We evaluated how actions based on the protocol were carried out when risk factors had been identified in mothers booked through the computer system in the maternity department of Homerton Hospital.

Method

The case notes of 2000 mothers delivered between 1 March 1990 and 29 March 1991 who had been booked on to the computer system at the Homerton Hospital were scrutinised after delivery by one of the authors (AY). The details examined included the booking history and examination and consequent antenatal care. Risk factors were scored as being present or absent or as missing information. Each of 38 possible clinical actions that might be carried out on the basis of risk factors identified at booking were recorded as having been performed or not. Risk factors were said to have been detected if printed on the

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computer antenatal report, hand written into the case notes, or mentioned specifically in correspondence between general practitioner and hospital. It is important to note that risk factors at the booking visit were considered independently of clinical response. For example, advanced maternal age (over 36) would be deduced from the woman's date of birth and date of booking rather than indirectly from the offer of amniocentesis, which might have been performed for other reasons (an abnormal ultrasound scan, for example).

A computer generated random sample of 100 of these case notes was then reviewed independently by another obstetric registrar (JL) for the same features. Four hundred and fifty two differences of opinion were identified between auditors (AY and JL) out of a possible 8400, giving a discrepancy rate of 5.4%. The κ statistic for risk factor detection was 0.78 and that for actions generated was 0.80, indicating good agreement (see appendix).

The ages of the 2000 women ranged from 14 to 52 years (mean (SD) 26.5 (5.6)). Gravidity ranged from 1 to 17 (2.8 (1.9)). Twenty five women were carrying twins. Nine hundred and three women (45.1%) were white, 892 (44.6%) were non-white, and ethnic origin was not specified in 205 (10.3%). Two hundred and thirteen women (10.7%) were not fluent in English; information on this point was not recorded in a further 276 (13.8%). Seven hundred and forty two women (37.1%) booked after 20 weeks; 535 women (26.75%) were deemed to have an "uncertain" gestation as their booking ultrasound scans were taken after 20 weeks' gestation and their menstrual history was suboptimal.

The protocols were analysed according to gestation at booking, the women's age, parity, birth order, ethnic origin, and uncertainty of gestational age. In addition, protocols were weighted by their perceived effect on clinical outcome. The opinions of five consultant obstetricians were sought; each was asked to score every combination of risk factor and action between 1 and 10, where 1 was thought of as an optional action of no special significance and 10 as an essential action whose omission would constitute serious negligence. This scoring allowed protocols to be divided into two groups according to the median score: those more and those less important.

Results

Of the 15 658 actions dictated by department protocols for the 2000 mothers, 3673 (23.5%) were actually

performed. The protocols least frequently fulfilled (<1% of actions) included: (a) screening for systemic lupus erythematosus when there had been a previous stillbirth or neonatal death, a late miscarriage or termination of pregnancy, preterm labour, or when a cervical suture had previously been inserted; (b) the measurement of urea, electrolytes, and uric acid at booking in the presence of proteinuria or when the patient had a history of eclampsia; (c) advice on early admission in labour if there was a history of precipitate labour; (d) organisation of a case conference at 35 weeks' gestation and regular urine chromatography for women who had admitted that they or their partners misused drugs; (e) discussion of epidural anaesthesia with nulliparous women aged over 35 at booking; (f) referral of mothers with proteinuria at booking to the consultant or to a specialist and the formation of a plan of action; and (g) a repeat scan if a significant discrepancy between dates and scan at 16 weeks was noted for mothers with inconsistent uterine size, a cycle length before the last period of over 30 days, a history of oral contraception stopped within three months of the last period, or uncertainty of more than two weeks about the date of the last period.

The only protocol that was followed in 100% of cases was counselling on drinking alcohol. In heavy smokers (defined as 10 or more cigarettes a day), 94.6% were advised to reduce their smoking, and placental function was checked in 61%. Placental function tests were carried out in women aged 36 or more (67.8%); those with parity ≥ 4 (64.4%); nulliparous women aged over 35 (89.7%); and women with blood pressure $\geq 140/90$ mm Hg at booking (80.0%). Of women with previous congenital fetal anomaly, 71.4% were offered an anomaly scan; 70.8% of women with fetuses at risk from haemoglobinopathy were offered haemoglobin electrophoresis. In all, 68.3% of women who misused drugs or whose partners were drug misusers and 67.5% women deemed at risk from HIV were screened for HIV; 63.6% of those women with a previous cervical suture were referred to a consultant and considered for another cervical suture. Of women found to have a pelvic or abdominal anomaly, 62.5% were referred to a consultant and had a plan of action organised; 60.5% women with vaginal bleeding had a cervical smear test.

Other compliance rates are of interest. Of women aged 36 or over, 44.5% had amniocentesis discussed with them, 45.2% had a midtrimester scan, and 40.4% were seen by a consultant between 28 and 32 weeks. Women with a previous stillbirth or neonatal death had their obstetric history validated in 25.5% of cases, were referred to a consultant in 42.5% of cases, and had a plan of action made in 44.7%. Of mothers who had had a previous fetus with a congenital anomaly, 14.3% were offered genetic counselling, 5.7% were offered chorionic villus sampling, and 8.6% were offered amniocentesis. Previous preterm labour led to referral to a consultant in 23.9% of cases and consideration of a cervical suture in 5.8%. A history of caesarean section, hysterotomy, or myomectomy led to validation in 41.8% of cases, discussion of the possible need for operative delivery in 23.4%, and advice on the need to report early in labour in 0.6%. Possible HIV infection in a mother led to screening for other sexually transmitted diseases in only 5.5% of cases.

The table shows that when the analysis was limited to the 63 of the total 126 combinations of risk factors and actions believed by the consultants to be of particular clinical significance the action rate rose to 28.3%. By contrast only 18.6% of protocols deemed less important were carried out ($p < 0.001$). Similarly, booking at or before 24 weeks' gestation was associated with greater compliance ($p < 0.001$). Maternal age at booking was also associated with increased compliance

Factors influencing compliance with protocols

	No of actions dictated by protocols	No (%) of actions performed	χ^2	df	p Value
Overall performance	15 658	3673 (23.5)			
Importance of protocols					
More important	7 853	2223 (28.3)	206.4	1	<0.001
Less important	7 805	1450 (18.6)			
Gestation at booking (weeks):					
< 24	10 082	2539 (25.2)	31.3	1	<0.001
> 24	772	125 (16.2)			
Maternal age (years):					
< 18	349	82 (23.5)	125.4	2	<0.01
18-35	12 947	2824 (21.8)			
> 36	2 366	767 (32.4)			
Parity:					
1	4 428	1048 (23.7)	0.152	1	>0.5
> 1	11 230	2625 (23.4)			
Birth order:					
1st	2 606	626 (24.0)	1.82	3	>0.5
2nd	3 782	866 (22.9)			
3rd	2 888	664 (23.0)			
≥ 4 th	6 382	1517 (23.8)			
Ethnic origin:					
White	6 809	1503 (23.2)	15.76	4	<0.005
Black	4 880	1216 (24.9)			
Asian	1 356	301 (22.2)			
Oriental	199	44 (22.1)			
Other/uncertain	866	167 (19.3)			
Uncertainty of gestation:					
Certain	4 804	1009 (21.0)	23.25	1	<0.001
Uncertain	10 854	2664 (24.5)			

($p < 0.01$), the major difference being accounted for by mothers aged 36 or over. Multiparity and increasing birth order did not affect compliance. The mother's ethnic group affected compliance significantly ($p < 0.005$), with black mothers having more and mothers of unknown or uncertain ethnic origin having fewer protocols performed.

Discussion

This is the first study in the United Kingdom to look objectively at compliance with existing departmental guidelines in an obstetric unit. In addition, specific factors affecting compliance have been examined. The low compliance echoes a number of other studies related to this topic. For example, primary care physicians at the Brigham and Women's Hospital, Boston, United States, failed to live up to their own recommendations for four of 14 screening procedures.⁵ Guidelines promulgated under the auspices of national medical speciality associations have often failed to stimulate the desired change in practice.⁶⁻⁸ Previous audits of obstetric practice in the United Kingdom judged the standard of work in two units according to ideals decided upon retrospectively; although both studies identified significant deficiencies in obstetric practice, no systematic analysis of the factors that could have been associated with these inadequacies was made.^{3,4}

In the present study risk factors and actions were assessed independently. While this is an objective approach, this type of assessment is obviously limited by the overlap between actions for the various risk factors. An action performed in later pregnancy may not necessarily have resulted from a risk factor noted at booking. For example, a request for ultrasonography may be initiated not because of a previous small baby but because of a current problem such as vaginal bleeding. Compliance will thus be overestimated.

It has been suggested that at least two assessors are necessary for audit because of wide interobserver variation.^{4,9} Such variation can reflect poorly defined protocols which allow a greater degree of subjective opinion,¹⁰ and there is no evidence that concordance is necessarily more correct than the work of a single auditor. The present study suggests that one auditor is sufficient and that verification, if considered necessary, can be achieved by corroborating a random sample of the main database rather than by duplicating the entire audit. It is probably more important that sufficient time is allowed for accurate data gathering. Indeed, this study was carried out by a full time researcher.

Compliance with protocols may reflect routine rather than selective obstetric practice. At Homerton Hospital, counselling on drinking and smoking was generally performed by midwives and minority health workers. A specially appointed HIV counsellor saw most of the antenatal patients. Blood samples for determining placental function were routinely taken in late pregnancy by the midwives. It is not surprising to find that more protocols were followed if mothers booked early rather than after 24 weeks, when fewer guidelines can be fulfilled. It is also gratifying to note that "more important" protocols were followed more often than "less important" ones. Older mothers and black mothers had a proportionally higher action rate and mothers of unknown or uncertain ethnic origin had a lower action rate. Parity and birth order made no difference to compliance.

Audit demands that standards be set,¹¹ and various methods to create practice policies have been described.^{12,13} Low compliance with guidelines may be associated with disagreement or simple ignorance of those guidelines. In the Homerton protocols, for

example, not all would agree that nulliparous women aged over 35 at booking should be counselled as to the need for epidural anaesthesia; this probably explains the action rate of 0%. Obviously, there is room for improvement, and this study identifies various areas in which such improvement might be made. Furthermore, compliance of 100% cannot be expected to occur without coercion and restriction of clinical freedom—for example, the decision to perform amniocentesis could be waived in accordance with the mother's wishes.¹⁴

Outcome measures (perinatal mortality and morbidity) at Homerton Hospital are similar to national averages for populations with a similar social and ethnic mix, and clinical performance at the Homerton is unlikely to differ significantly from that of other units. Detailed study would probably reveal that many maternity units have low levels of compliance with protocols, should these exist.

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Appendix

The extent of agreement between observers can be assessed using the unweighted κ statistic where all disagreements were arbitrarily regarded as having equal importance.¹⁵ The κ statistic provides a measure of agreement after exclusion of the proportion of agreement expected by chance. It is calculated by the formula $\kappa = P_o - P_e / 1 - P_e$ where P_o is the observed proportion of agreement and P_e is the proportion of agreement expected by chance. The value of P_o is calculated by adding the numbers in the congruent cells and dividing by the total number of comparisons made. The components of P_e are calculated as a proportion of patients assigned to each category by one observer, multiplied by the proportion assigned to the corresponding category by a second observer. The results so obtained in each category are then added and divided by the total number of comparisons to obtain P_e . Another way of expressing κ is $1 - q_o/q_e$ where $q_o = 1 - p_o$ and $q_e = 1 - p_e$.¹⁶

Kappa can vary from +1, indicating perfect agreement, to 0, indicating agreement no greater than expected by chance, and can assume negative values up to -1 when agreement is less than expected by chance. Values over 0.6 indicate good agreement.¹⁷

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