AUDIT IN PRACTICE

THIS WEEK . . .

• In the first article Wiener *et al* audit all mid-trimester amniocenteses performed at a district general hospital during three years, examining number of attempts at withdrawing amniotic fluid, number with bloodstained liquor, and number of subsequent miscarriages, terminations, and congenital abnormalities, as well as the cost of the audit. Though the audit provided useful information on complication rates, the authors recommend that because of its high cost—about £5 per record audited—such monitoring should not be carried out continuously.

• In the second article Colver reports that monitoring the implementation of a health surveillance programme for preschool children and reporting the results back to the primary health care teams improves child health.

• In the commissioned article Dr Bennett and Mr Walshe review their experience with occurrence screening, which will form the basis of a trial of medical audit in Brighton Health Authority.

Audit of amniocentesis from a district general hospital: Is it worth it?

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Abstract

Objective—To audit all mid-trimester amniocenteses performed by obstetricians at a district general hospital to see whether experience improved the outcome.

Design—Retrospective review of medical records.
Setting—Royal Gwent Hospital, south Wales.

Subjects—All 469 amniocenteses carried out in 1985-7.

Outcome measures—Number of attempts at withdrawal of amniotic fluid; number with bloodstained liquor; and number of subsequent miscarriages, terminations, and congenital abnormalities.

Results—Of the 469 amniocenteses, 411 were performed by one obstetrician, and initial comparisons with those performed by the rest of the hospital team showed no significant differences in outcome of pregnancy. The main difference between the two groups was in the number of attempts at withdrawal of amniotic fluid and the number with bloodstained liquor. The single obstetrician failed to obtain amniotic fluid on 1% of occasions compared with 10% for the other operators by the end of the second attempt. The costs of carrying out the audit were considerable. The review of fewer than 500 case records cost the equivalent of £2000 in staff time and took over 200 hours to complete, equivalent to 63 sessions of one person's time.

Conclusions—The audit was useful in that it provided information on complication rates, which could be compared with published data, and comparisons between obstetricians who perform large and small numbers of procedures.

Implications—For an individual's practice the monitoring of amniocentesis should not be continuously carried out and subsequent audits should tackle other common procedures. When an audit is attempted the health service should provide adequate support to clinicians for this purpose.

reports.^{1,5} This report describes a comparison of one obstetrician experienced in performing amniocenteses (JJW) with others in a district general hospital from January 1985 to December 1987, during which time 10 652 women were delivered. The aim of the study was to audit the practice of amniocentesis in terms of fetal losses and complications so that advice could be given to patients on the risks of the procedure. In addition the practical difficulties of manual auditing were assessed.

Method

All mid-trimester (15-23 weeks) amniocenteses performed by a group of obstetricians at the Royal Gwent Hospital in 1985-7 were analysed. One obstetrician (JJW) was experienced in amniocentesis, having performed over 700 during the previous seven years. A sample of 2-12 ml of amniotic fluid was withdrawn using a 22 French gauge spinal needle immediately after ultrasonic assessment of the easiest access point to an amniotic pool. All Rh negative patients were given 250-500 IU of anti-D. At the time of the procedure the number of attempts at amniocentesis and whether the liquor was contaminated with blood were noted.

All patients were seen either one or four weeks after the procedure depending on whether the indication for amniocentesis was for amniotic fluid α fetoprotein estimation and cholinesterase electrophoresis or for chromosomal analysis. At this visit the fetal heart rate or movements, or both, were recorded and any complication noted. After pregnancy the case notes were examined for details of outcome by a record clerk and the information entered on a form checked by a clinician.

The time taken by clinicians to enter and check data and by clerks to retrieve and transfer data was costed to calculate the cost of the audit. The data were analysed using the SPSSX statistical package by an epidemiologist.

Results

Four hundred and sixty nine mid-trimester amniocenteses were carried out. Comparisons were made between 411 carried out by one obstetrician

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Introduction

The risks of amniocentesis have been assessed in various studies in both low risk¹ and high risk pregnancies.² Most studies have been multi-investigator

(JJW) and the 58 performed by other obstetricians, including the consultant, senior registrar, registrar, and locums.

Table I shows the number of attempts at withdrawal of amniotic fluid in the two groups and the results of the first and second attempts. After two attempts four patients (1%) had had no liquor withdrawn by JJW and six (10%) by the other obstetricians; eight of these patients had liquor successfully withdrawn at the third attempt.

TABLE 1—Number (percentage) of attempts at amniocentesis and results of first and second attempts

	JJW (n=411)	Other obstetricians (n=58)	p Value*
No of attempts:			
1	386 (94)	40 (69)	
2	23 (6)	12 (21)	<0.01
3	2 (0.5)	6 (10)	
Colour of liquor at 1st attempt:			
Clear/yellow	354 (86)	41 (71)	
No fluid	23 (6)	8 (14)	<0.001
Brown	21 (5)	0	
Red	13 (3)	9 (16)	
Colour of liquor at 2nd attempt:			
No 2nd attempt	386 (94)	40 (69)	
Clear/yellow	9 (2)	9 (16)	
No fluid	4 (1)	6 (10)	<0.001
Brown fluid	1 (0.2)	1 (2)	
Red/pink	11 (3)	2 (4)	

*χ² test.

TABLE 2—Profile of women undergoing amniocentesis

	No of women
Social class:	
I	4
II	87
III	86
IV	36
V	3
Indications:	
≥35 years	170
Raised α fetoprotein	147
Low α fetoprotein	60
History of chromosomal abnormality	36
Others	28
Abnormality on ultrasonic scan	14
History of neural tube defect	14
Gestational age (weeks):	
15-16	126
17-18	275
19-20	60
21-23	8

Table II shows the social class, indications for amniocentesis, and gestational age at amniocentesis of the whole group. No occupation was recorded for 253 women, so social class could be analysed only for 216. Table III shows the age of the women undergoing amniocentesis seen by JJW and the other obstetricians. It also shows the outcome of pregnancy.

Vaginal bleeding occurred after 10 amniocenteses by one obstetrician (JJW) and after none by the other obstetricians. Miscarriages after amniocentesis were divided into early (during the first 28 days) and late (after 28 days but before 28 weeks' gestation). There were eight miscarriages, four early and four late, after JJW's amniocenteses and none after those carried out by the other obstetricians. In the women with early miscarriages one amniocentesis was performed for raised maternal serum α fetoprotein concentration and three because the women were aged over 35. In two brown amniotic fluid was obtained, indicating a previous intrauterine bleed. In the women with late miscarriages one amniocentesis was carried out because of age (41 years), one because of severe oligohydramnios on ultrasound scan, and two because of raised maternal α fetoprotein concentrations. In one of these four brown amniotic fluid was obtained. Rupture of the membranes after amniocentesis occurred in two of the JJW series: one of these miscarried and in the other the pregnancy continued.

TABLE 3—Mother's age at amniocentesis and outcome of pregnancy. Values are numbers (percentages)

	JJW (n=411)	Other obstetricians (n=58)	p Value*
Maternal age (years):			
15-24	97 (24)	9 (16)	
25-29	74 (18)	20 (35)	<0.01
30-34	55 (13)	11 (19)	
35-37	75 (18)	6 (10)	
38-39	61 (15)	5 (9)	
40-44	49 (12)	7 (12)	
Outcome of pregnancy:			
Live births	383 (93)	52 (90)	
Stillbirths	3 (0.7)	2 (4)	NS
Therapeutic abortions	16 (4)	4 (7)	
Early miscarriage	4 (1)	0	
Late miscarriage	4 (1)	0	
Not known	1 (0.2)	0	

*χ² test.

TABLE 4—Type of congenital abnormalities and terminations

	No	No of terminations
Structural:		
Central nervous system abnormalities:		
Neural tube defects	7	7
Other	1	1
Renal abnormalities	5	2
Gastrointestinal abnormalities:		
Gastroschisis	2	2
Omphalocele	1	1
Diaphragmatic hernia	1	1
Other abnormalities	5	1
Chromosomal abnormalities:		
Trisomy 21	2	2
Triploidy	2	2
XXY	1	1
Metabolic abnormalities	1	0
Normal	441	0
Total	469	20

The overall percentage of congenital malformations was 5.9% (table IV).

Overall the audit took over 221 hours at an estimated cost of over £2200. Retrieving case notes and completing coding sheets took 83 hours, checking coding sheets 50 hours, punching eight hours, data validation 40 hours, and data analysis 40 hours. This was equivalent to about £5 per record audited.

Discussion

There were no significant differences between the two groups of obstetricians in outcome, in particular in the number of terminations of pregnancy, miscarriages after amniocentesis, or babies born with congenital abnormalities. The main difference between the single operator (JJW) and others was in the percentage of amniocenteses successfully performed at a single attempt (94% v 68%). Clear fluid was obtained in 86% of cases by JJW compared with 71% by the other obstetricians, blood stained taps in 3% compared with 16%, and no fluid in 6% compared with 14%. Among all patients who had either one or two attempts JJW failed to obtain fluid in 1% compared with 10% for the other obstetricians.

The working party on amniocentesis showed that operator experience influenced the numbers of attempts,² as did the study by Young,⁶ but in Young's series there was no difference in outcome. Other studies have suggested that the operator's experience does influence outcome,^{5,7} though a report from Denmark showed no difference in pregnancy outcome and number of taps with experience.¹ A Canadian study reported that more than two insertions and a needle size of 19 French gauge or greater increased the number of spontaneous abortions.⁴ Successful attempts at obtaining liquor were more related to size of the uterus than to the experience of the operator.

The difficulty with the study reported here is its size and its inadequate power to exclude small differences between the obstetricians with any confidence. If we had started by asking what sample size would be necessary to show a difference between, say, a 95% rate of successful amniocentesis at the first attempt by the experienced operator and, say, a 90% rate among the other obstetricians with a power of 90% set at a probability level of 0.05 then we would have needed over 700 cases in each of the two groups. If we were attempting to differentiate between postamniocentesis miscarriage rates of, say, 1.7% and 2% between the two groups we would have needed several thousand cases. The study itself included all the amniocenteses performed over three years by an obstetric team in one busy district general hospital, which illustrates the problem of such small scale audits.

Another problem is that of selection bias, which may lead to substantial patient differences in the two

groups. Women undergoing amniocentesis differed in age distribution from all pregnant women seen over the three years: among the amniocentesis group 24% were aged under 25 and 41% aged 40 or over whereas among all pregnant women 40% were under 25 and 6% 40 or over. Amniocentesis was performed on 3% of pregnant women under the age of 35 and on 33% of those aged 35 or over. Local screening policies advise amniocentesis on all women whose serum α fetoprotein concentration is more than 2.5 multiples of the median. In older women amniocentesis is recommended for those over 38 and is offered to those over 35. Social class differences between those undergoing amniocentesis and all pregnant women are difficult to assess because the partner's occupation was not recorded, and 253 of the 469 women undergoing amniocentesis had no recorded occupation. Among the remainder the two largest occupational classes were professional and technical workers (teachers and nurses) in social class II and clerical workers in social class III. Women in social class II had the greatest number of amniocenteses for age over 35 years. There were significant differences between the social class of those undergoing amniocentesis (42% social classes I and II) and the population of south Gwent as a whole (17% social classes I and II).

Intergroup comparisons showed that the ages of women were clearly different, with 45% aged over 35 for JJW compared with 31% for the others (table III). This may have been by chance or because of some referral preference on the part of the patient or member of staff. Those who had had a previous amniocentesis may have been referred back to the single operator, and this was more likely to have been the case than with the other operators, some of whom were junior staff in training.

In this study there were four miscarriages within 28 days of amniocentesis and a further four after 28 days, all in the single operator group, and a total of five stillbirths. This total fetal loss of 2.7% is low taking into consideration a background miscarriage rate (after demonstrating a live fetus in the first trimester) of 2%⁸ and a rate among women aged 35 years or over of 4.3%.⁹ The low fetal loss reported in this series occurred despite there being a higher than normal number of older women. Fetal loss after amniocentesis in reported controlled studies^{1,4} was the same as in the control group (3.5% and 4.7%). In other controlled series the excess fetal loss in the amniocentesis group had been reported as 1%¹ and 1.1-5%.² In uncontrolled studies³ fetal losses of 3.1%⁵ and 0.5%¹⁰ have been reported.

Twenty four of the amniotic fluid samples were stained brown. None of the pregnancies resulting in stillbirth had discoloured amniotic fluid, but in three of the eight miscarriages brown amniotic fluid was obtained. The colour of the amniotic liquor is the variable that Hanson *et al* found significant for adverse outcome.¹¹ The National Institute for Child Health and Development study found no relation between blood staining and fetal loss, but brown staining was related to an unfavourable outcome of pregnancy.¹ Tabor *et al* also found an increased risk of miscarriage when discoloured fluid was obtained, although they did not comment about the exact colour.¹ Golbus *et al* concluded that greenish brown amniotic liquor was due to aged blood pigment.¹²

What distinguishes this review from earlier approaches at clinical review using case histories was the systematic nature of the activity, the opportunity it provided for comparisons with the clinical performance of others, and the potential for changes in practice. The

white paper emphasises the need for medical audit, and it is important to assess the costs and benefits when this is carried out manually by an individual clinician. At the rate of one session a week the 221 hours this study took would take nearly 15 months to carry out. Entry of the original data on to a microcomputer at the time the procedure was carried out would have reduced the overall cost, though data on pregnancy outcome would still have needed entering later. In regions where microcomputer systems have been introduced the problem is that of specifying at the outset the minimal clinical data set that is to be computerised. Although this leads to difficulties, it also leads to discussion and agreement about which outcome measures are the most critical when evaluating a particular service. Attempts at costing such systems are somewhat speculative but a computerised audit system for amniocentesis should be 50%-70% of the cost of the manual audit system.

On the benefit side, the audit has made it possible to begin to measure the risk of various adverse outcomes in the hands of an experienced operator and others who carry out the procedure less often. The outcomes were not significantly different but the experienced obstetrician required fewer attempts at obtaining liquor. An audit such as this cannot measure the costs of such unnecessary attempts in terms of time, pain, and anxiety. It raises a question about who should carry out procedures such as amniocentesis where there is a measurable risk. Although there may be merits in this work being carried out by someone who will be associated with the team over a long period, the training needs of registrars must be accommodated.

Having completed a manual audit of amniocentesis, we do not recommend that this should become a regular practice. It would be more valuable to study some other common diagnostic or therapeutic procedure before returning to amniocentesis. Isolated audit is to be encouraged when it is carried out by individuals who genuinely wish to find out answers to specific questions. For it to be recommended on a large scale the revolution in information technology must become visible on the shop floor.

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