The diagnosis of pregnancy in general practice

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SUMMARY. In 1,631 pregnancies presenting to general practitioners, the reliability of three proprietary slide tests for the diagnosis of pregnancy was assessed both against the outcome and against the results of hospital tests done at the same time. When all patients were considered the reliability of such tests done in the surgery was 85 per cent against a 90 per cent for hospital tests and when only patients who were more than 42 days pregnant were included, the accuracy figure rose to 87 per cent in general practice and 91 per cent in hospital.

The time delay before the results of the hospital test was assessed showed a mean of three days which is considered unacceptable if there are urgent clinical reasons for the test being done. The doctors participating listed their reasons for doing tests and in 54 per cent of cases urgent confirmation or otherwise of the pregnancy was considered essential by either doctor or patient. In the remaining 46 per cent this confirmation was considered simply helpful rather than essential. The study showed that the accuracy of the test, when delegated to a nurse, was acceptable and that in a proportion of three to one the participating doctors considered that the test was of value and worthwhile in patient care.

Introduction

In 1972 the Dundee Local Medical Committee considered the possibility that pregnancy diagnostic test equipment should be provided for general practitioners by the National Health Service. It was agreed that a pregnancy test could thus be carried out in the surgery in less time than was required to transport the urine sample to the laboratory and that most patients for whom this test was required were those who were particularly anxious to know the result. For those reasons some general practitioners had equipped themselves with pregnancy diagnostic sets—at their own expense—but could not recover the cost of such equipment through fees charged to the patients.

The Scottish Home and Health Department were asked by the Scottish General Medical Services Committee to consider making pregnancy diagnostic sets available to general practitioners, but this request was refused. The Scottish Home and Health Department made reference to a report of the Board of Science of the British Medical Association (1970) which stated that ". . . the performer of the test should be suitably trained and experienced in reading the test " and that " many doctors would not have the time nor the capacity to do them (the tests) and others would feel rightly, that the time and trouble taken would not be worthwhile ".

The Dundee Local Medical Committee disagreed and the Research Committee of the Scottish Council of the Royal College of General Practitioners was approached for help in the design of a study which could assess the value of such tests. This committee asked the West of Scotland Faculty of the Royal College of General Practitioners to complete a study of the accuracy and value of pregnancy diagnostic test equipment in general practice.

Immunological pregnancy diagnostic tests

Human chorionic gonadotrophin (HCG) is produced by trophoblastic tissue in large quantities during the first three months of pregnancy. The hormone is present in significant concentration in the urine by 35 days after the last menstrual period, reaches a maximum at about the tenth week of pregnancy and falls thereafter to the twentieth week. The immunological pregnancy tests are designed to detect a level of HCG in the urine.

Two groups of immunological tests are available—slide tests (latex flocculation) which take

about two minutes to complete and the tube tests (haemagglutination) which can be read between two to ten hours. In the slide test, flocculation occurs when a suspension of latex particles on which HCG has been adsorbed is mixed with a corresponding antiserum. Flocculation does not occur if the antiserum has been mixed with urine containing free HCG (as in pregnancy) as antibodies have thus been neutralised. The manufacturers of slide tests claim that an accurate diagnosis of pregnancy can be made from the twelfth to the fourteenth day after the first missed menstrual period by testing either early morning or mid-stream urine samples.

The slide tests used detect concentrations of HCG greater than 2,000 units per litre. The mean value of urinary HCG during pregnancy five weeks after the last menstrual period is 3,000 units per litre with an expected range of one to 12,000 units per litre.

During the past ten years there have been many reports of the diagnostic accuracy of both slide and tube tests, the effect of proteinuria and the timing of the urine sample on the accuracy of the test.[1,5–14] Apart from papers by Grob *et al.* (1968) and Grob and Gibbs (1970) all published reports are from hospital laboratories.

In a review of pregnancy diagnosis Hobson (1969) found a wide range of accuracy when the same immunological test was used in different laboratories. ' Gravindex ' had an accuracy of 70–89 per cent, in the confirmation of pregnancy and 92–100 per cent in non-pregnant women. Corresponding figures for ' Pregnosticon ' (a tube test) were 86–100 per cent in pregnant and 97–100 per cent in non-pregnant women. Horwitz *et al.* (1972) reported accuracies for pregnant and non-pregnant women of 98·8 per cent for ' Pregnosticon ' haemagglutination test, 96·7 per cent for ' Planotest ' slide test and 93·8 per cent for ' Gravindex ' slide test. These workers considered that slide tests were inaccurate before the fiftieth day of pregnancy.

Most studies showed that of the slide tests ' Planotest ' had the greatest diagnostic accuracy. In a study from general practice, Grob *et al.* found that ' Planotest ' had an accuracy of 99·01 per cent in pregnancies of less than ten weeks, and 100 per cent in later pregnancies. No false positive results were reported. False negative results are most likely to occur if the test is done before the fortieth day of pregnancy and false positive results at or near the menopause if concentrated early morning urine is used for the test.

The tests used in this study were ' Gravindex ' (Ortho Pharmaceuticals) ' Prepurex ' (Wellcome Reagents Ltd.) and ' Planotest ' (Organon Laboratories).

Method

General practitioners were drawn from the five Scottish Faculties of the Royal College of General Practitioners and 155 participated in the study (West of Scotland Faculty, 41 general practitioners, South-east Faculty 48, East of Scotland Faculty 16, North-east Faculty 45, and North of Scotland Faculty five). Each doctor was supplied with a 20-test pack of one of the slide tests, 20 numbered and five un-numbered recording forms. All women between the ages of 16 and 45 years, for whom the confirmation of pregnancy was considered necessary by the doctor or the patient, were included in the study.

At the patient's first consultation, parts A and C of the recording form were completed. A mid-stream urine sample was obtained at the time of consultation if the patient had not brought a sample with her. When facilities did not exist in the practice for obtaining a mid-stream specimen an early morning urine sample was brought by the patient the following day. The sample was divided into two parts, one of which was tested in the surgery, the other being sent to the appropriate hospital laboratory for a pregnancy diagnostic test.

Part D of the recording form was completed when the result of the hospital test was known and parts C and D were then returned to the recorder. Part B was completed eight weeks after the initial consultation, returned to the recorder and matched with parts C and D through the serial number. Part A of the form—the patient's name and address—was retained by the family doctor.

Results

The study was started in July 1973 and was concluded after one year, when few newly completed forms were being returned. Of the total of 3,100 forms issued, 1,631 were returned (52 per

cent). Some doctors had difficulty in completing all 20 tests, but this was not related to particular faculties or areas of the country.

The accuracy of completed forms was high—all forms were checked for missing information which was subsequently obtained from the family doctor by letter or telephone. In the majority of cases this proved satisfactory. The data were punched on 80-column cards and analysed during September and October 1974. Punching errors were few—the greatest error in any one item of information was 0·5 per cent.

Patients admitted to the study

Marital status was recorded for 1,622 of the completed forms (99·4 per cent)—83·9 per cent of patients were married and 14·9 per cent single (table 1). The age distribution of patients was as expected, with the greatest number (58·2 per cent) between 20 and 30 years (table 2). The duration of pregnancy at the time of the first consultation showed an even distribution between 35 and 63+ days (table 3).

TABLE 1
MARITAL STATUS OF PATIENTS (n=1622)

	Number	*Per cent*
Married	1,362	*83·9*
Single	241	*14·8*
Widowed	4	*0·3*
Divorced	15	*1·0*

TABLE 2
AGE OF PATIENTS (n=1622)

Age	*Number*	*Per cent*
< 19 yrs.	240	*14·8*
20–24 yrs.	505	*31·2*
25–29 yrs.	440	*27·1*
30–39 yrs.	294	*18·1*
> 40 yrs.	143	*8·8*

TABLE 3
INTERVAL BETWEEN CONSULTATION AND DATE OF LAST KNOWN MENSTRUAL PERIOD (n=1626)

Days	*Number*	*Per cent*
35–41	250	*15·4*
42–48	366	*22·5*
49–55	277	*17·0*
56–62	258	*15·9*
63+	402	*24·7*
Not known	73	*4·5*

Reasons for pregnancy tests in the surgery

Eleven possible indications for the pregnancy test were detailed on the recording form, and doctors were asked to indicate all the reasons they thought appropriate for each patient; 2,375 reasons were recorded (1·5 reasons per patient) and were subsequently divided into four groups (table 4). Group A—situations when the doctor might consider an immediate pregnancy test essential for good clinical care—contained 337 (14·2 per cent), Group B—an immediate diagnosis considered helpful, but not essential—203 (8·5 per cent), Group C—patient might consider an immediate diagnosis important—958 (40·3 per cent) and Group D—patient might consider an immediate dignosis helpful but not essential—877 (36·9 per cent).

TABLE 4
INDICATIONS FOR PREGNANCY TEST

	Number	*Per cent*	*Per cent of total*
Group A: Doctor may consider immediate pregnancy test necessary for good clinical care			
" Drug therapy contraindicated if patient pregnant "	48	*14·2*	*2·0*
" Threatened or missed abortion "	92	*27·3*	*3·9*
" Termination considered "	179	*53·1*	*7·5*
" Rubella contact or immunisation "	12	*3·6*	*0·5*
" Ectopic pregnancy "	6	*1·8*	*0·3*
	337		*14·2*
Group B: Immediate diagnosis considered helpful but not essential			
" Irregular menses "	203		*8·6*
Group C: Patient considers immediate diagnosis important.			
" Possible pregnancy associated with contraception "	156	*16·3*	*6·6*
" Patient wants to know urgently "	665	*69·4*	*28·0*
" Amenorrhoea related to menopause "	107	*11·2*	*4·5*
" Undue post-partum amenorrhoea "	30	*3·1*	*1·3*
	958		*40·3*
Group D: Patient considers immediate diagnosis helpful but not essential			
" Simple amenorrhoea "	877		*36·9*
	2375	*100*	*100*

Urine samples

A mid-stream specimen of urine brought by the patient or passed at the time of consultation was obtained from 598 patients (36·5 per cent). The remainder—1,041 patients—had an early morning specimen of urine tested. Proteinuria as detected by ' Uristix ' was found in 37 urine samples (2·3 per cent).

Pregnancy tests

' Planotest ' was used in 615 tests (37·7 per cent); ' Prepurex ' in 671 (41·2 per cent) and ' Gravindex ' in 343 (21·1 per cent). Of all tests, general practitioners performed 1,188 (72·8 per cent), nurses 386 (23·7 per cent) and receptionists or secretaries 56 (3·4 per cent) tests.

Results of tests

The test results were designated positive (no flocculation), negative (flocculation present) and inconclusive. For all the tests done in general practice, 965 (59·2 per cent) were positive; 632 (38·8 per cent) negative; and 32 (1·9 per cent) inconclusive (table 5). All but one of the inclusive reports were subsequently withdrawn by the participating doctors.

The outcome of each suspected pregnancy was determined. Pregnancy was confirmed in 864 patients (53 per cent) of whom 169 (19·5 per cent) aborted, or had the pregnancy terminated medically. Of the 765 patients for whom pregnancy was not confirmed, a pathological condition (such as hydatidiform mole) was reported in nine cases (1·1 per cent).

Comparison of surgery tests with outcome

Table 6 shows the comparison of surgery and hospital tests with outcome for all patients in the study. Correct answers were obtained in 1,365 (85·6 per cent) of surgery and 1,429 (90·5 per

TABLE 5

RESULTS OF SURGERY TESTS (n=1629)

Test	*Positive*		*Negative*		*Inconclusive*		*Total*
		%		%		%	
'Planotest'	369	*60·0*	227	*36·9*	19	*3·1*	615
'Prepurex'	374	*55·8*	286	*42·6*	11	*1·6*	671
'Gravindex'	222	*64·7*	119	*34·7*	2	*0·6*	343
TOTALS	965	*(59·2)*	632	*(38·8)*	32	*(2·0)*	1,629

TABLE 6

COMPARISON OF ALL SURGERY AND HOSPITAL TESTS WITH OUTCOME

	Surgery tests		*Hospital tests*	
		%		%
Correct results	1,365	*85·6*	1,429	*90·5*
False positives	83	*5·2*	26	*1·7*
False negatives	115	*7·2*	97	*6·1*
Inconclusives	32	*2·0*	27	*1·7*
				$\ddot{J}$=0.8226
TOTALS	1,595		1,579	

TABLE 7

COMPARISON OF SURGERY TESTS AND HOSPITAL TESTS WITH OUTCOME—PATIENTS MORE THAN 42 DAYS PREGNANT

	Surgery tests		*Hospital tests*	
		%		%
Correct results	1,117	*87·4*	1,158	*91·2*
False positives	56	*4·4*	22	*1·7*
False negatives	82	*6·4*	69	*5·4*
Inconclusives	23	*1·8*	21	*1·7*
TOTALS	1,278		1,270	

TABLE 8

ANALYSIS OF RESULTS OF ALL TESTS—DOCTOR AND NURSE

	'Planotest'		*'Prepurex'*		*'Gravindex'*	
		%		%		%
Doctor: Correct answer	384	*86·8*	403	*85·7*	230	*88·1*
False positive	21	*4·8*	20	*4·3*	10	*3·8*
False negative	25	*5·7*	40	*8·5*	19	*7·3*
Inconclusive	12	*2·7*	7	*1·5*	2	*0·8*
	442		470		261	
$\ddot{J}$	0·7716		0·7128		0·7040	
		%		%		%
Nurse: Correct answer	132	*83·0*	101	*77·7*	71	*93·4*
False positives	13	*8·2*	14	*10·8*	2	*2·6*
False negatives	7	*4·4*	14	*10·8*	3	*4·0*
Inconclusives	7	*4·4*	1	*0·7*	—	
	159		130		76	
$\ddot{J}$	0·7387		0·5659		0·8684	

cent of hospital tests. Table 7 gives the same figures for all tests, surgery and hospital, for patients more than 42 days pregnant. Correct answers were obtained in 87·4 per cent of surgery and 91·1 per cent of hospital tests.

Comparison was made of the results of each of three pregnancy tests against the outcome for the tests performed by the doctor and nurse in the practice (table 8).

TABLE 9

RELIABILITY OF TESTS DONE BY SECRETARIES AND RECEPTIONISTS

	Number	*Per cent*
Correct results	44	*78·6*
False positive	3	*5·4*
False negative	7	*12·5*
Inconclusive	2	*3·5*
	56	

TABLE 10

FREQUENCY OF FALSE NEGATIVE RESULTS (SURGERY TESTS)

Time since last menstrual period	*Total number of tests done*	*False negatives* Number	%	*Per cent of all false negatives*
35–41 days	250	27	*11·0*	*23·5*
42–48 days	366	36	*10·0*	*31·3*
49–55 days	277	21	*7·7*	*18·3*
56–62 days	258	9	*3·3*	*7·8*
63 +	402	16	*4·0*	*13·9*
Not known	73	6	*8·5*	*5·2*
	1,626	115		

Jouden's index (J) was used as an assessment of the reliability of each type of surgery test, and for all hospital tests. Table 9 shows the reliability of tests done by receptionists—78·6 per cent accurate; 5·4 per cent false positive and 12·5 per cent false negative. False negative results were more likely to occur before 42 days of pregnancy. Table 10 gives the surgery false-negative results for all tests related to the duration of pregnancy: for patients less than 42 days false negative results account for 11 per cent of the tests and 6·7 per cent after this stage. The false positive rate was lowest in those approaching the menopause (2·8 per cent) and there was no clear relationship between the percentage of positive false results and the age of the patient (table 11).

TABLE 11

FALSE POSITIVE RESULTS (SURGERY) RELATED TO AGE OF PATIENT

Age of Patient	*Total number of tests done*	*False positives* Number	%	*Per cent of all false positives*
19 yrs.	240	18	*7·8*	*21·7*
20–24 yrs.	505	25	*8·6*	*30·1*
25–29 yrs.	440	17	*3·9*	*20·5*
30–40 yrs.	294	19	*6·5*	*22·9*
40 yrs.	143	4	*2·8*	*4·8*
	1,622	83		

Time delay before the result of hospital tests was known

The time delay between the patient's consultation and the result of the hospital test being known was established for 1,608 patients. The average time delay for all patients was 2·9 days and the delay was also estimated for groups of reasons given for the surgery test and for some possibly urgent indicators (table 12). There was little variation in the delay before the hospital test result was known for individual indications.

The participating doctors were asked to give a subjective opinion of the value of each test done, and in a ratio of three to one thought that the provision of an immediate pregnancy diagnosis was of value (table 13).

TABLE 12

TIME DELAY BEFORE RESULT OF HOSPITAL TEST KNOWN

Indications for test	*Mean time delay*
All patients	2·85
Group A (doctor might consider immediate diagnosis necessary)	3·0
Group B (immediate diagnosis helpful, not essential)	2·8
Group C (patient considers immediate diagnosis important)	2·8
Group D (patient considers immediate diagnosis helpful)	2·7
" Patient wants to know urgently "	2·84
" Threatened or missed abortion "	2·94
" Termination considered "	2·84
" Rubella contact or immunisation "	2·83
" Possible ectopic pregnancy "	2·83

TABLE 13

SUBJECTIVE OPINION OF VALUE OF TEST

	Extremely valuable	*Valuable*	*Little value*	*No value*	
' Planotest '	159	300	125	29	
' Prepurex '	159	321	117	71	
' Gravindex '	87	160	59	34	
All tests	405	781	301	134	
		1,186		435	1,621
		2·7		1	

Discussion

The purpose of this study was to determine the value of the immunological pregnancy slide test to the general practitioner and whether this test when immediately available to the doctor was a practical alternative to the hospital laboratory test. For this to be so, several criteria must be met. The reliability of the surgery test should approach that of the hospital laboratory and there must be justifiable reasons why the test should be immediately available to both the doctor and his patient. Finally it must be seen that doctors consider that the test justifies the time taken for it to be done in the surgery.

In this study the hospital tests showed a total reliability of 90·5 per cent which increased to 91·2 per cent when patients less than 42 days pregnant were excluded. Both of these figures represent the cumulative analysis of hospital laboratories throughout Scotland, using a variety of pregnancy tests and as such, represent the reliability that the general practitioner can expect from what is the only facility open to him to obtain a pregnancy test for his patients.

These hospital figures are lower than the accuracy levels reported in other published papers, and show a reliability of 0·8226 for all tests done when assessed by Jouden's index (the closer

$\dot{J}$ approaches 1, the more reliable the test). The average time delay before the results of the hospital test was known was three days and there was little variation in this figure for different clinical indications for the test. A delay of three days is acceptable for some of the less urgent reasons stated by the doctors, but is unacceptable for indications such as " threatened or missed abortion " if good clinical care is to be given.

The reliability of surgery tests was 85·6 per cent for all tests done and 87·4 per cent for patients more than 42 days pregnant. Although lower than hospital tests, the difference of 3·8 per cent does not seem large enough to indicate that the tests should be done in hospital rather than in the practice. In both the tests done in the surgery and in hospital, the numbers of false negatives and inconclusive results are markedly similar—the difference in reliability seems to be in the number of false positive results—4·4 per cent in practice and 1·7 per cent in hospital. In the surgery tests the false positive results are evenly distributed over all age groups of patients, and are not restricted to those at or near the menopause when such results might have been expected (table 11).

The reliability of each of the three types of slide test used in the surgery was assessed by Jouden's index, and assessments were made of the person doing the test. The reliability of the doctor with ' Planotest ' was 0·77 with ' Prepurex ' 0·71 and with ' Gravindex ' 0·70. When performed by a nurse reliability figures of 0·74 (' Planotest '), 0·79 (' Prepurex ') and 0·87 (' Gravindex ') were obtained. It seems likely that all tests were equally reliable when used by the doctors but ' Gravindex ' was the more reliable test when this work was delegated to the nurse. None of the contributing doctors or nurses had had previous training in the use of these kits, and as each doctor was issued with only one set of 20 tests there was no opportunity for any individual to gain reasonable experience in its use. It must be anticipated that the reliability of tests done in the surgery would be likely to improve as the experience of those performing the tests increased.

The manufacturers of all these slide tests recommend that tests should not be done on patients less than 40–42 days after the last normal period. In the surgery tests the percentage of false negative results was highest in those who were less than 42 days pregnant (table 10) but accurate results were obtained in 76 per cent of these patients. It seems therefore that there is no need to delay all tests until after 42 days after the last menstrual period, but negative results in tests done before that date should indicate that the tests should be repeated ten to 14 days later.

TABLE 14
TEST RESULTS AGAINST OUTCOME—E.M.U. AND M.S.U.

	EMU		*MSU*	
		%		%
Accurate result	896	*86·1*	509	*85·1*
False positive	61	*5·9*	28	*4·7*
False negative	65	*6·2*	52	*8·7*
Inconclusive	19	*1·8*	9	*1·5*

TABLE 15
RESULTS OF TESTS FOR URINES CONTAINING PROTEIN (AS DETERMINED BY ' URISTIX ')

	Proteinuria		*No proteinuria*	
		%		%
Accurate result	29	*82·9*	1,334	*85·6*
False positive	2	*5·7*	81	*5·2*
False negative	1	*2·9*	114	*7·3*
Inconclusive	3	*8·6*	29	*1·9*

This study confirmed the statement of the manufacturers that it is immaterial whether an early morning concentrated urine or a randomly obtained mid-stream urine is tested (table 14).

For both types of urine samples the reliability of the slide tests was the same. The few urine samples that contained protein (2·3 per cent) compared with the finding that false positive results were given by five per cent of these urines as compared with a total false positive rate for surgery lists of six per cent, support the view that simple proteinuria does not affect the test result (table 15).

The indications for doing an immediate pregnancy test range from ' simple amenorrhoea ' where there is not any valid medical reason to ' Rubella contact or immunisation ', where it might be considered essential that a rapid pregnancy diagnosis is established if the patient is to be cared for correctly. The indications noted in this study were further grouped into two main categories—those that might be considered essential by doctor and patient, and those where the diagnosis would be simply of value to either doctor or patient. The first group (essential indicators) accounted for 54 per cent of all reasons given, but it can be argued that the availability of rapid immunological pregnancy tests means that the test should be considered when either doctor or patient considers it of importance to know the result. It thus seems that all the indications for doing this test were to a greater or lesser extent justifiable.

Contributing doctors assessed the test as of value in patient care. It is true that many practices have equipped themselves with pregnancy diagnostic test sets, but it seems unreasonable to expect that they should continue to bear the cost. The pregnancy slide test is reliable when done in the surgery by a doctor or nurse and there are good and sufficient reasons why this test should be immediately available in the surgery. In the majority of patients in this study, a diagnosis was thought necessary at an early stage of pregnancy before a confident diagnosis could be made on clinical grounds.

It is hoped that this diagnostic aid will be regarded as a necessary tool for the general practitioner and as such, will be made available by the National Health Service to those who wish to use it. This study has yielded more information than is presented in this paper; further aspects of the diagnosis of pregnancy in general practice will be reported later.

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