COMPARISON OF ANTI-HCV TESTS USING ABBOTT AND ORTHO TEST KITS

(A MULTI-CENTRE TRIAL)

SUMMARY OF RESULTS OF PHASE I OF THE TRIAL

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1. INTRODUCTION

1.1 The study to compare the results of testing blood donor samples using anti-HCV tests provided by Abbott and Ortho has been performed at three Regional Transfusion Centres (RTCs) Glasgow (South West Scotland), Northern and North London.

1.2 Testing the same blood donor samples with both tests was Phase I of the trial; Phase II consists of additional tests on those samples which were found repeatably positive by both Abbott and Ortho tests which will be carried out in specialist laboratories.

1.3 Each RTC received sufficient tests for approximately 3,500 donor sample tests during the period September/October 1990.

1.4 The initial test kits supplied by Ortho were found at the North London RTC to give negative control OD results which invalidated the quality control of the plate. The Company were advised and the test kits were replaced by another batch. Substitution of the test kits was also carried out at the other two RTCs, although at Northern RTC the negative control ODs of the first batch of test kits were well within the quality control limits. A single kit lot number was used at Glasgow RTC, and at the Northern RTC. Three different lot numbers were used at N. London RTC.

1.5 Modification of the computer programme for the Abbott Commander System installed at the North London RTC had to be undertaken by the company to allow the tests to proceed satisfactorily.

1.6 At the Northern RTC, abbot installed a Parallel Processing Centre (PPC) specifically for the trial. The % cut-off values using this equipment varied between 0.413 and 0.547 which was higher than the OD of between 0.3 and 0.4 predicted by Abbott. On the one occasion that the equipment which had been in use at the RTC regularly for several months was used to perform the tests, the cut-off value was 0.383. Also, on this date the OD values for the positive control sera were virtually identical compared with greater variability with the PPC installed for the trial. This PPC may have had a minor fault but without inclusion of quality control panels the effect of this could not be evaluated. Cut-off values at Glasgow and North London RTC were consistently below an OD of 0.4.

1.7 All three RTCs reported that the tests were easy to perform and that the manufacturer's instructions were "user friendly". All tests were performed according to these instructions.

1.8 Northern RTC commented that the lack of a suitable computer package for the statistical analysis of the

Abbott tests resulted in many manual calculations having to be carried out.

They also commented that the ADAMS assay data analysis and management systems used by Ortho had some operational problems because of its lack of flexibility in coping with the method of distributing samples onto the plates used at the RTC. Some blank wells read as positives and corrections had to be made. However, the plate reactive sample matrix report was useful for selecting initial screen positives and the control summary report and the daily reactive summary report were valuable. The ability to use wells in an required number makes the system versatile and cost-effective.

2. SUMMARY OF RESULTS USING ABBOTT AND ORTHO TESTS

2.1 These results are presented in Table 1 and Figure 1 and in percentage terms in Figure 2.

2.2 It can be seen that the number of initial screen positives obtained with the Ortho test is higher than with Abbott tests but the repeatable positive rate was similar with both tests at Newcastle and North London RTCs. The repeatable positive rate for Abbott tests at Glasgow RTC was higher than that for Ortho (Figure 2).

2.3 The difference in the rate for initial screen positives is not statistically significant. However, if this trend occurred in the routine screening of 2.5 million donations it would result in a considerably greater cost, not only for the purchase of an increased number of Ortho test kits, but also in staff time involved in withdrawing into quarantine the initial screen positives and repeating the tests on a subsequent occasion.

3. COMPARISON OF REPEATABLE POSITIVE RESULTS USING ABBOTT AND ORTHO TESTS

3.1 The comparisons are shown in Table 2 and in Figure 3 in percentage terms.

3.2 It can be seen from these comparisons that the two test kits identify two population of donor samples which overlap. Samples positive with both test kits are only one-half to one-third of the total repeatable positive samples.

3.3 It is hoped that the resolution of a truly positive anti-HCV result can be obtained during the second phase of the study.

4. REFERRAL OF REPEATABLY POSITIVE SAMPLES

4.1 A total of 69 samples (Glasgow 25, Northern 25 and North London 19) were referred to each of the three specialist laboratories.

ntre	No. Samples Tested	ABBOTT ISP*	(%)	RR**	(%)	ORTHO ISP	(%)	RR	(%)
ASGOW	3516	18	(0.51)	18	(0.51)	23	(0.65)	14	(0.40)
RTHERN	3539	13	(0.37)	12	(0.34)	25	(0.70)	21	(0.59)
LONDON	3578	14	(0.39)	13	(0.36)	16	(0.44)	15	(0.42)
otal	10633	45	(0.42)	43	(0.40)	64	(0.60)	50	(0.47)

ISP - Initial Screen Positive
RP - Repeatable Positive

TABLE 1

i . screen and repeatable positives using Abbott and Ortho anti-HCV sts at three RTCs

FIG. 1: REPEAT REACTIVES v ALL TESTS

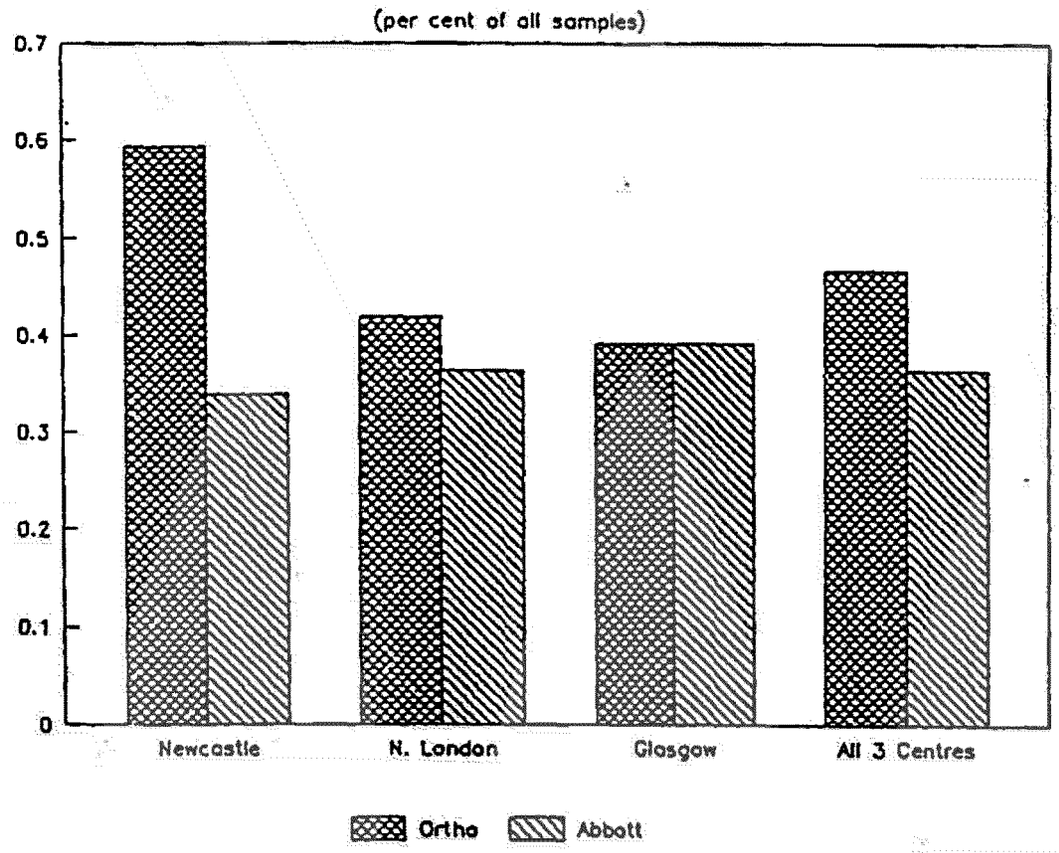
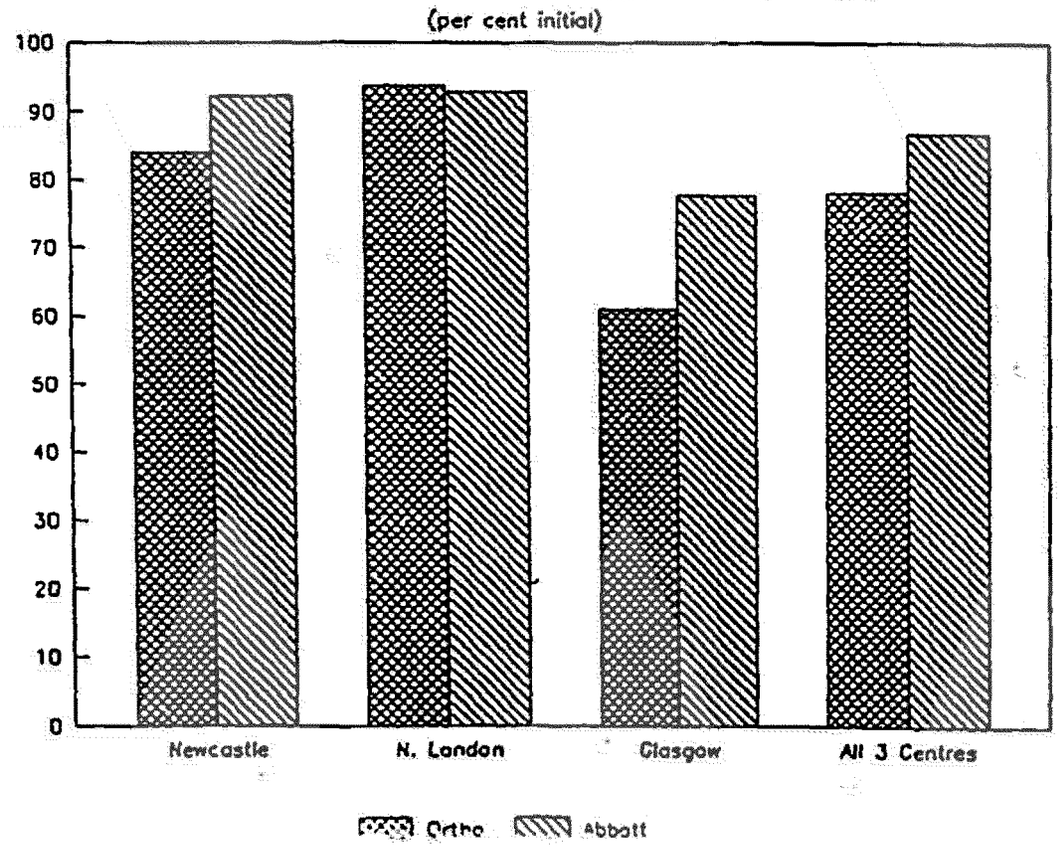


FIG. 2: REPEAT v INITIAL REACTIVES



entre	REPEATABLE POSITIVES				
	No. Samples Tested	No. Abbott Positve only	No. Abbott and Ortho Positve	No. Ortho Positive only	Total
LASGOW	3516	9	9	7	25
ORTHERN	3539	4	8	13	25
. LONDON	3578	4	9	6	19
otal	10633	17	26	27	69

TABLE 2

alysis of repeatable positive results using ABBOTT and ORTHO anti-HCV sts in three RTCs.

FIG. 3: ANALYSIS OF REPEAT REACTIVES