

16 SEP 1997



12th September 1997

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To: All NBS Consultants responsible for the HCV Lookback

Dear Khin

For your information, I thought you may be interested in receiving a hard copy of the slides I used for my presentation on the HCV Lookback at BBTS Warwick last week, which give you an idea of the progress achieved to date.

Best wishes.

Yours sincerely

GRO-C

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DoH Advisory Committee MSBT

**Expert Ministerial Advisory Committee on
Microbiological Safety of Blood and
Tissues for Transplantation
Policy Making Body ----> Mandatory Screening Tests**

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UKBTS/NIBSC Liaison Group

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(Chairman Dr W Wagstaff)

Red Book Executive Committee (Expert Professional Advisory Body to UK Transfusion Services, Guidelines & Standards)
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WP on Labels

WP on Barcoding

WP on
Histocompatibility



Background to UK HCV Lookback

1. October 1991 - UK wide HCV antiB screening MSBT decision
- no lookback
2. August 1994 SACTTI Ad Hoc meeting recommendation for
HCV lookback
3. September 1994 MSBT considered SACTTI recommendation -
> core group to report back
4. December 1994 MSBT considered report
Outcome: agreed duty of care to recipients infected with HCV
5. January - October 1995 MSBT Ad Hoc HCV Lookback
Working Party - Procedures, Guidelines, Research



1995 Chapter of events UK HCV Lookback

- 11th Jan - Ministerial announcement**
Helpline*, DoH Epinet cascade, NBS cascade
- 16th Jan - Panorama “Bad Blood”**
PHLS* ‘worried well’ testing for multitransfused
- 18th Jan - Preliminary action for BCs**
- 20th Jan - 1st Ad Hoc HCV MSBT Meeting**
- 6th Feb - Phase 1 RTC action**
- 31st Mar - Full RTC package**
- 3rd Apr - CMO HCV Lookback letter**
Trace, counsel and if necessary treat - “How to do it”

- * by 13th February -**
 - > 13,000 calls to Helpline**
 - > 1,000 PHLS ‘worried well’ tests**



HCV Lookback

“We shall do all we can to care for patients who have become infected in this way through counseling and, where appropriate, treatment.”

Extract from statement by Tom Sackville, 11/1/95



Algorithm for Lookback for HCV- 1

Routine anti-HCV ELISA Screening



Repeat Reactive Donor Identified



HCV Positivity confirmed RIBA, PCR



Donation Record Reviewed



Components not issued
to hospitals or returned
unused to BTS - NO
FURTHER ACTION



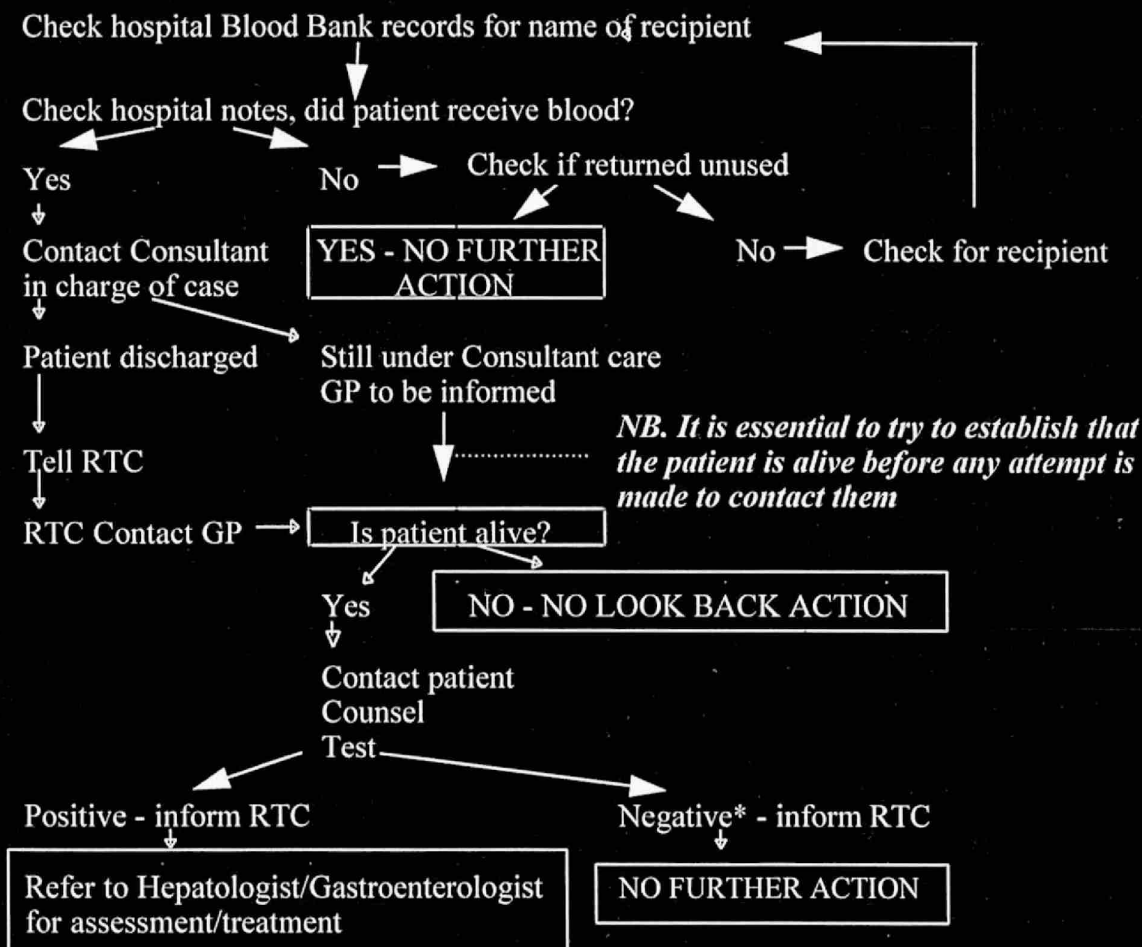
Blood sent to hospitals



Contact Consultant Haematologist in charge of Blood Banks at relevant
hospitals with donation number and date of issue to hospitals



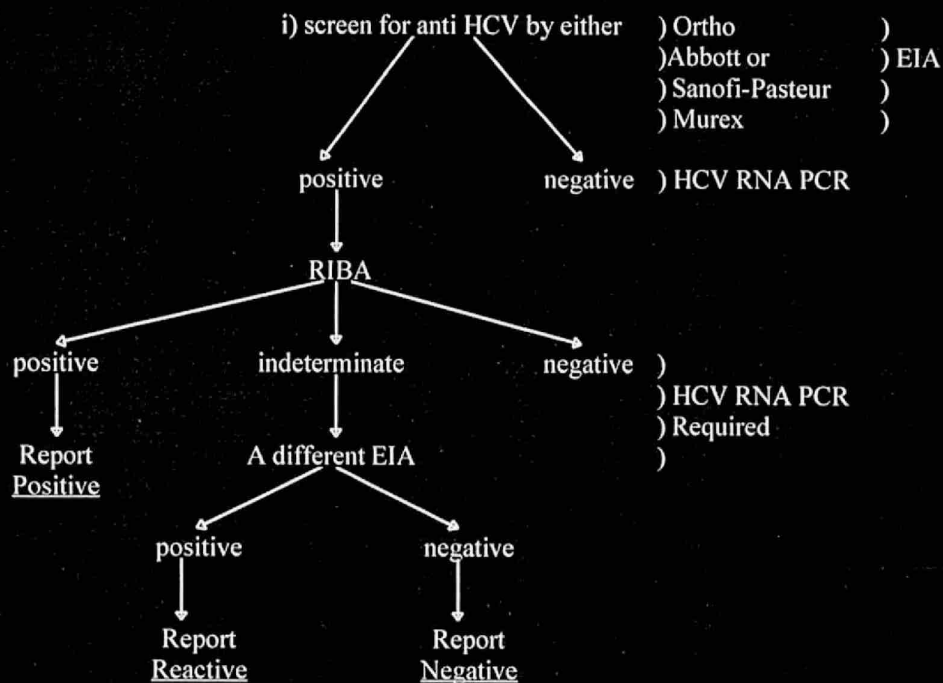
Algorithm for Lookback for HCV- 2



*If patient is immunocompromised, ELISA may give a false negative result and PCR may be required.



HCV Lookback - Testing Algorithm



ii) Screen for anti HBc by EIA/RIA

iii) Repeat anti HCV EIA



Definition of HCV Indeterminate for inclusion in Lookback

9

RIBA clear band 3+ c22 or NS3 (c33c)
assess EIAs

Results available from 2 different EIAs

include: -

sera reactive in 2 generically distinct EIAs

exclude: -

sera negative in 1 EIA

Results available from 1 EIA

include: -

sera negative in single EIA

Include irrespective of PCR result



Current Status of Lookback

	England	Scotland	Wales	N Ireland	UK Total
Number of donors identified who had given blood pre 1991	2135	564	93	17	2809
Number of components identified and notified to hospitals	8118	2128	815	120	11181
Number of recipients identified by hospitals	4963	857	409	56	6285
Number of recipients who have died	3202	507	227	31	3967
Number of recipients followed up	4902	849	333	75	6159
Number of recipients counselled and tested	1261	171	55	22	1509
Number of recipients tested positive	667	106	33	10	816
Number of recipients tested negative	557	65	18	12	652

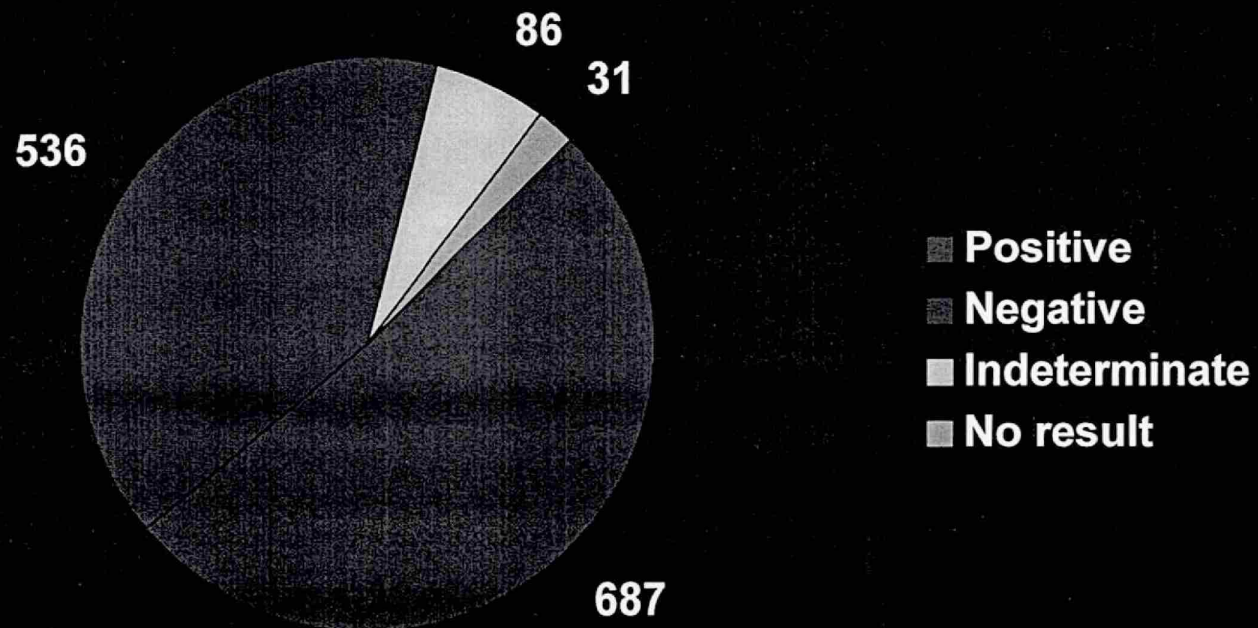


HCV Lookback National Database - as at 1/9/97

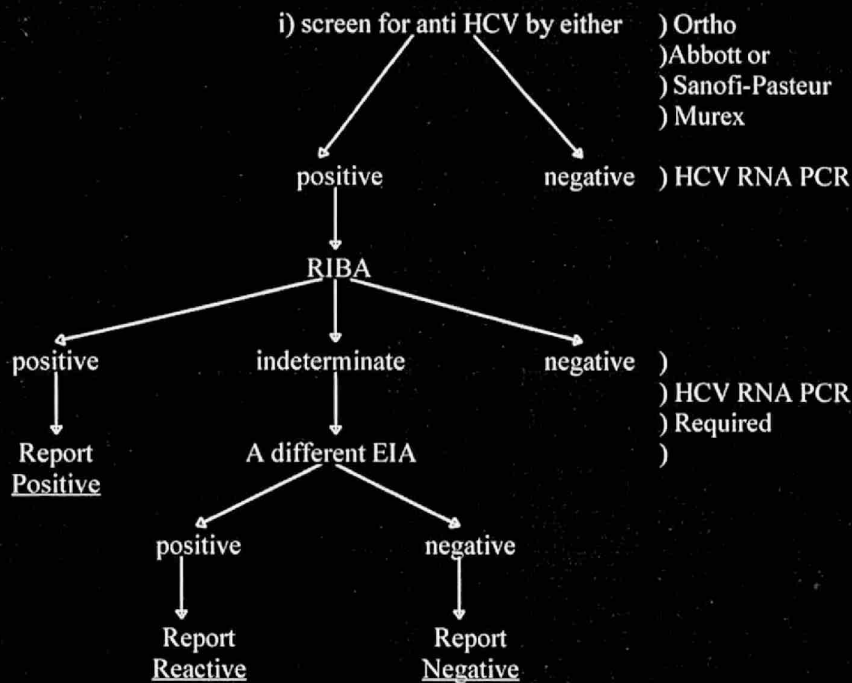
Total positives	687
Total negatives	536
Total indeterminates	86
Total no results	31
	<hr/>
Total cases	1340



Results summary



HCV Lookback - Testing Algorithm



ii) Screen for anti HBc by EIA/RIA

iii) Repeat anti HCV EIA



HCV POSITIVE Data

Result	HCV EIA	HCV RIBA	HCV PCR	Total
POS1	+	+	+	343
POS2	+	+	-	
or	+	+	No result	
or	No result	+	No result	230
POS3	+	-	+	
or	+	Indet	+	
or	+	No result	+	
or	No result	+	+	94
POS4	Indet	Indet	+	
or	-	-	+	
or	-	No result	+	
or	Indet	No result	+	
or	No result	No result	+	20
			Total	687

HCV Lookback - Central Database 1/9/97



HCV NEGATIVE Data

Result	HCV EIA	HCV RIBA	HCV PCR	Total
NEG1	-	-	-	
or	-	No result	-	
or	No result	-	-	464
NEG2	-	-	No result	
or	-	No result	No result	
or	No result	-	No result	72
			TOTAL	536

HCV Lookback - Central Database 1/9/97



HCV INDETERMINATE Data

Result	HCV EIA	HCV RIBA	HCV PCR	Total
INDET	+	Indet	-	
or	+	-	-	
or	+	-	No result	
or	+	No result	-	
or	+	No result	No result	
or	Indet	Indet	-	
or	Indet	-	-	
or	Indet	+	-	
or	-	Indet	-	
or	-	+	-	
			TOTAL	86

HCV Lookback - Central Database 1/9/97



HCV Lookback

Further assessment and follow up

All anti-HCV positive patients should be referred to a specialist with an interest in the condition for further assessment. This will usually involve a period of observation and, in most cases, a liver biopsy. Patients considered to be at risk of progressive liver disease may be offered treatment with interferon.

Extract from CMO's letter to GPs, 3/4/95

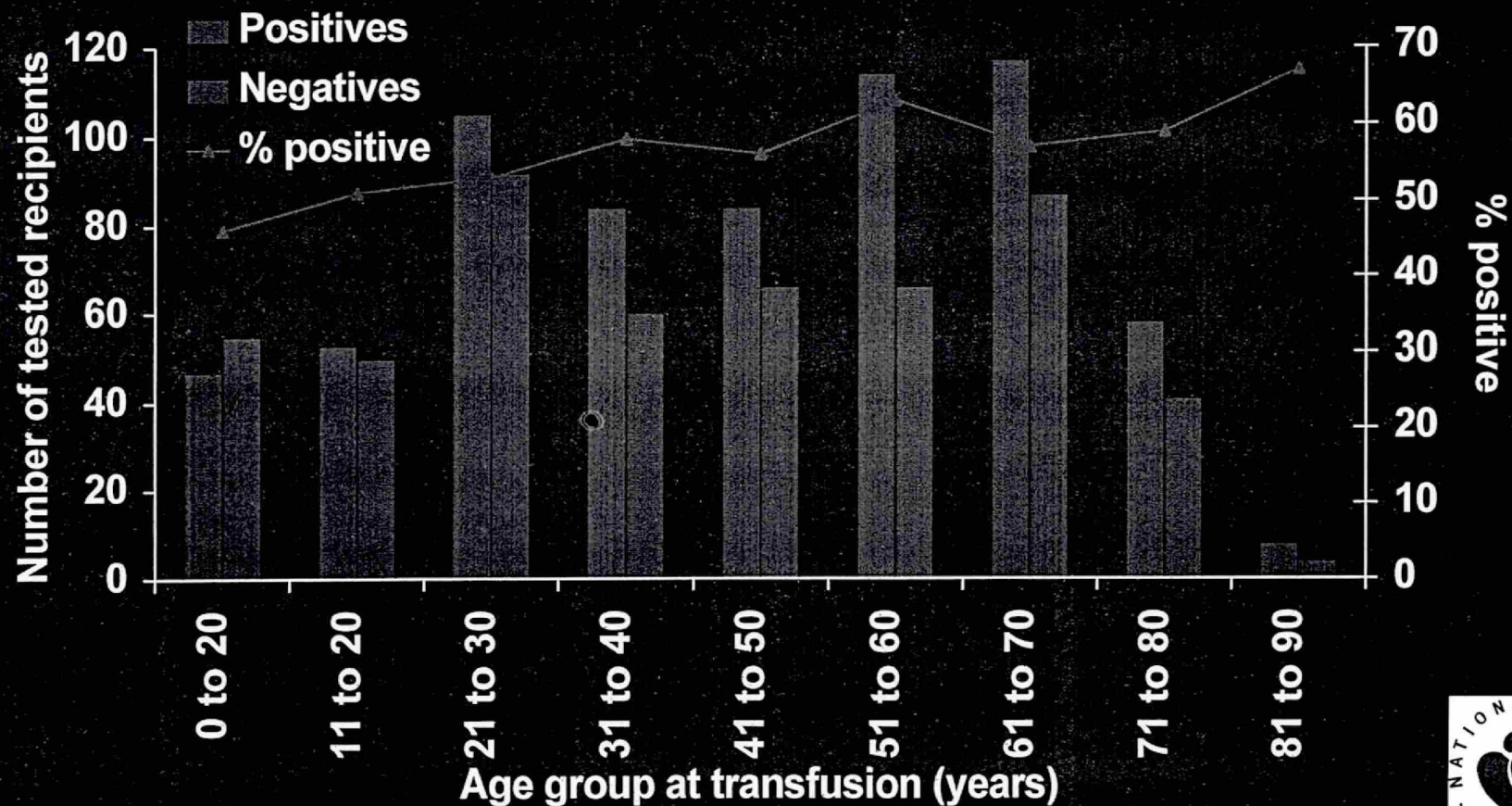


Positive Recipients

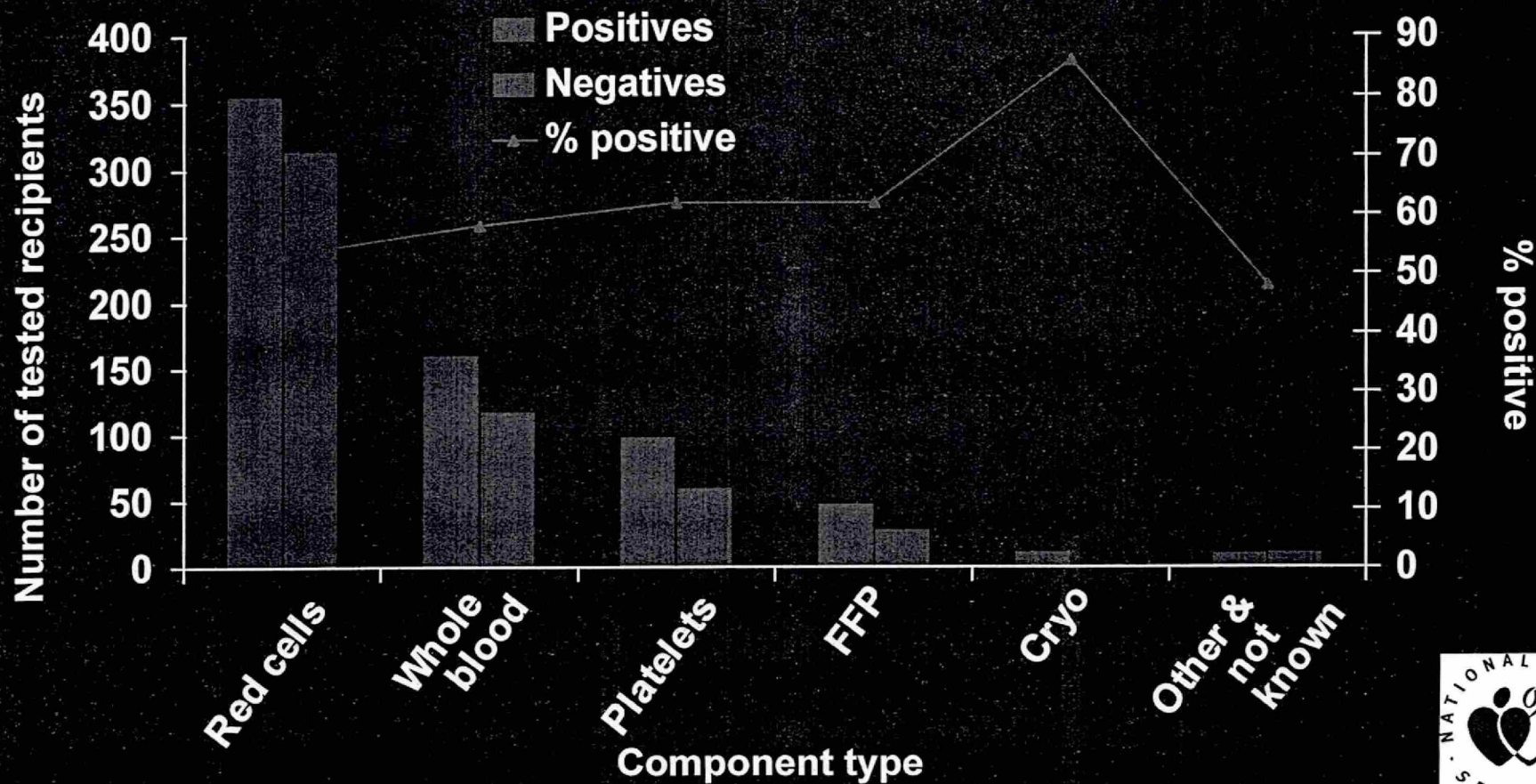
- ◆ 687 positives - 341 male, 335 female and 11 unknown
- ◆ 384 positive recipients have children (211 female recipients, 169 male, 4 unknown)
- ◆ Ethnic origin -
 - 578 white
 - 12 Indian/Pakistani/Bangladeshi
 - 9 black Caribbean
 - 4 black African
 - 3 oriental
 - 6 other
 - 75 not known



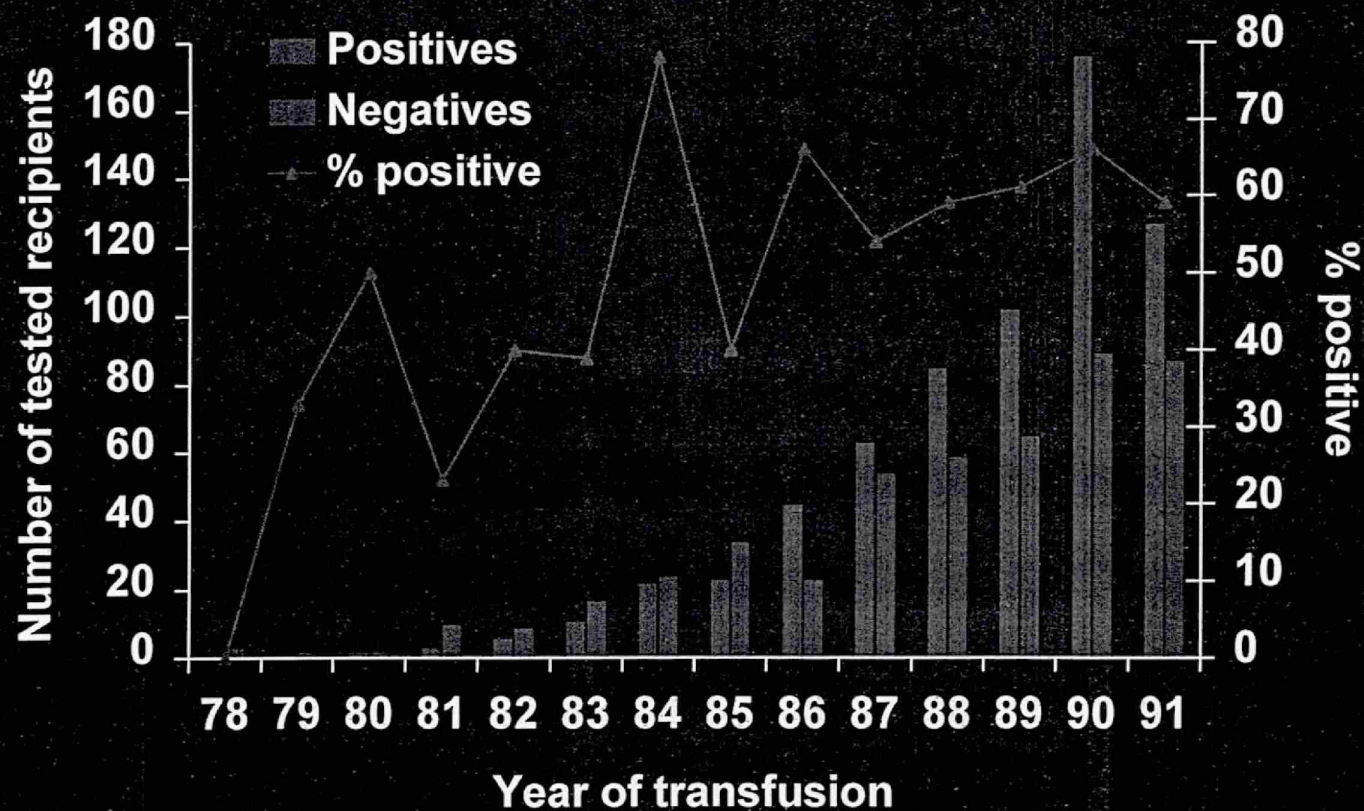
HCV test outcome by age groups of recipients



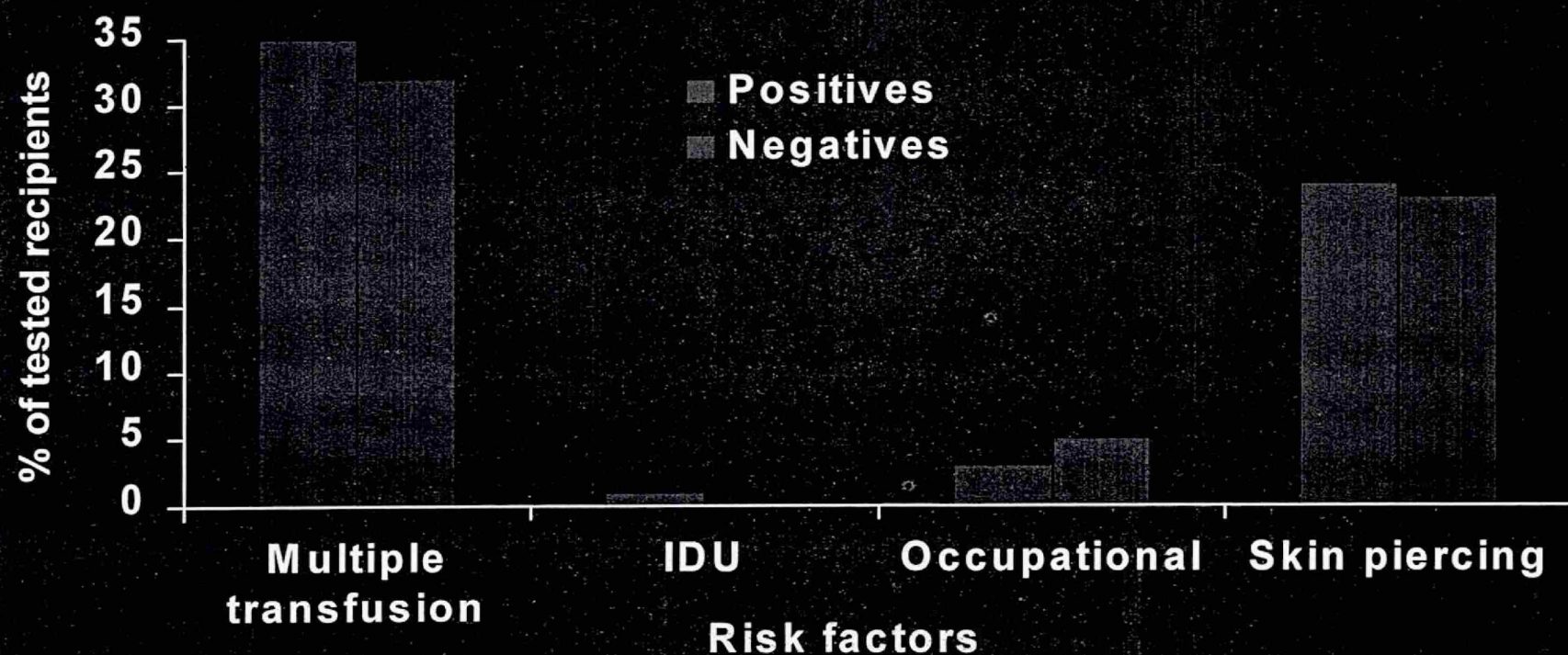
HCV test outcome by component type



HCV test outcome by year of transfusion



% of tested recipients with other risk factors



Evidence of liver disease

**Information supplied to the database
indicates that of the 687 positives 32
(4.66%) have evidence of symptomatic
liver disease**

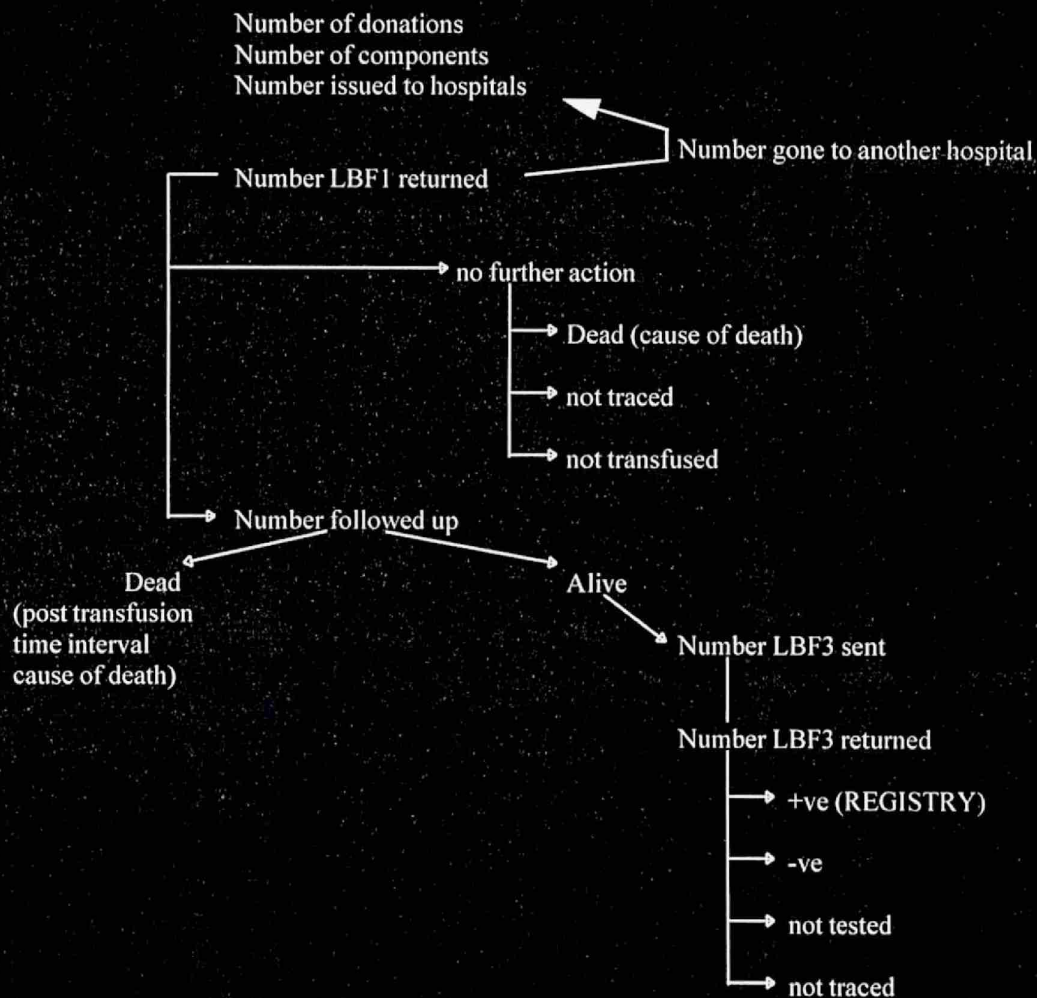


Abnormal LFT results

HCV test (N)	Bilirubin		ALT		AST		Albumin	
	N	%(95% CI)	N	%(95% CI)	N	%(95% CI)	N	%(95% CI)
Positive		55% tested		69% tested		57% tested		57% tested
symptomatic (32)	3	21% (5-51)	5	33% (12-62)	4	31% (10-61)	1	8% (0.2-39)
asymptomatic (655)	9	2% (1-5)	90	20% (16-23)	51	13% (10-17)	12	3% (2-6)
All (687)	12	3% (2-5)	95	20% (16-24)	55	14% (11-17)	13	3% (2-6)
Negative		45% tested		56% tested		47% tested		48% tested
asymptomatic (534)	6	2% (1-5)	3	1% (0.2-3)	3	1% (0.3-4)	4	2% (0.4-4)
Indeterminate		68% tested		73% tested		54% tested		68% tested
asymptomatic (84)	2	4%(0.5-12)	4	7% (2-16)	2	4%(0.5-15)	0	0%



HCV Lookback Overview



NBA/CDSC - National registry “known date” HCV infection

- ◆ Monitor natural history long term outcome of HCV infection
- ◆ Estimate times from HCV infection to biochemical/histological/clinical HCV related illness and death
- ◆ Monitor numbers of new infections
- ◆ Provide a shared national/international resource for designing future studies

Angela Robinson 1/9/96



Further work

- ◆ multivariate analysis of factors that may effect transmission
- ◆ describe biases in the sample of recipients tested
- ◆ natural history of HCV in recipients



With thanks to.....

- ◆ Dr E Love
- ◆ Dr N Anderson
- ◆ Dr V James
- ◆ Dr K H Shwe
- ◆ Dr V Martlew
- ◆ Dr A Townley
- ◆ Dr C E Chapman
- ◆ Dr H Gabra
- ◆ Dr A Dike
- ◆ Dr P Flanagan
- ◆ Dr P Hewitt
- ◆ Dr S Knowles
- ◆ Dr E Caffrey
- ◆ Dr F Boulton
- ◆ Dr T Wallington
- ◆ Dr J A F Napier

