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CLINICAL TRIALS

Definition

A randomised clinical trial (RCT) is an experimental study design in which subjects are randomly allocated to groups which either do (treatment group) or do not (control group) receive a treatment being trialed. The groups are compared in terms of outcome. The outcome will vary, but often involves recovery from established disease or some measure of improved health status. The study design must ensure differences in outcome between groups can be ascribed to the intervention.

The distinguishing feature of a randomised clinical trial is that investigators allocate exposure.

Historical Development

The development and application of clinical trials is a phenomena occurring post World War II. James Lind and Benjamin Rush documented early clinical experimentation.

- 1753 James Lind - Scurvy
- 1794 Benjamin Rush - Bloodletting
- 1948 Medical Research Council - Streptomycin treatment of tuberculosis
- Mid-1960's common practice in the pharmaceutical industry

Types of Clinical Trials

Preventative (primary prevention): evaluation of an agent or procedure that reduces the risk of developing disease among those free of the condition at enrolment. Subjects can be individuals (Francis field trial, 1954) or entire populations (Newburgh-Kingston dental caries study, 1950).

Therapeutic (secondary prevention): evaluates patients with a particular disease to determine the ability of an agent or procedure to diminish symptoms, prevent recurrence or decrease risk of death from that disease (Coronary artery surgery study 1983).

Classification of Clinical Trials

Prior to release, a drug proceeds through several phases, classified as follows:

Phase I. Safety and pharmacological profiles: The introduction of a candidate vaccine or drug into a human population to determine its safety, dose, mode of action and route of administration.

Phase II. Pilot efficacy studies: Initial clinical examination to assess efficacy.

Phase III. Extensive clinical trial: A complete assessment of safety and efficacy. Usually involves large numbers, random allocation to treatment and control groups, and may be a multicentre trial.

Phase IV. Post marketing surveillance (in the pharmaceutical industry): This phase is conducted after the national drug registration authority has approved the drug for distribution or marketing. May include exploration of a specific pharmacological effect, determine the effects of long term use, or establish the incidence of adverse reactions.

Issues in the Design and Conduct of RCTs

There are a number of issues to consider in the design and conduct of clinical trials to ensure validity of results.

The Study population

The study population is a sub-group of a reference population, the group of people for whom the investigator wishes the results to be applicable. Several factors are considered when selecting the study population, including the following:

- obtain a sufficient number of subjects within the reference population
- choose a study population that will experience a sufficient outcomes of interest within a reasonable period of time
- consider the logistics of obtaining complete and accurate follow up information on all study subjects for the duration of the trial.

Allocation to treatment and control groups

Random assignment means that each individual has the same chance as another of receiving either the intervention or the 'control'. Randomisation removes potential bias due to individual responsiveness of subjects to the intervention, by equal distribution of people to treatment and control groups. This makes it likely that both groups will be comparable with regard to baseline characteristics and potential confounding variables.

Allocation to treatment and control groups takes place after eligibility and acceptance of the subjects has been determined. Improvement in a treatment subject may arise because of:

- changes in measurement (regression to the mean)
- the natural history of the disease
- the 'Hawthorne effect' (observation producing change)
- a placebo effect
- the treatment itself.

Maintenance and assessment of compliance

Compliance requires the active participation and co-operation of study subjects. Non-compliance may affect the detection of a true effect of study treatment. It is necessary to ensure the control group does not receive the intervention being trialed by other means, as this would obscure the effect of treatment.

Strategies to enhance compliance:

- selection of a group motivated to comply because of increased risk for the disease
- use groups who may be potentially more interested and reliable than others
- make frequent contact with participants
- use incentives to encourage participation.

Measures used to assess compliance include:

- self reports
- pill counts
- laboratory tests for biochemical markers.

Ethical Considerations

There is a strong relationship between ethics and methodology. It is unethical to recruit subjects for a study known to be deficient or unlikely to produce valid results. Additionally, individuals should not be denied access to treatment known to be effective, to participate in a clinical trial. Pre-determined rules decide whether a trial should be terminated in cases such as increased risk of adverse events, or greater than anticipated benefit.

Role of the Ethics Committee

The ethics committee protects the rights and welfare of human subjects involved in research, by previewing study protocols. The ethics committee is guided by the Declaration of Helsinki and the NH & MRC Statement on Human Experimentation and Supplementary Notes.

Declaration of Helsinki (global)

An agreement signed in Helsinki, Finland in 1975 by 35 countries, and last amended in October, 1996. In medicine, it refers to the ethics of clinical research, consent, human experimentation and other ethical questions.

NH & MRC Statement on Human Experimentation & Supplementary Notes (local)

A document issued by the National Health and Medical Research Council (NHMRC) which guides the activities of ethics committees, and details issues to be observed by sponsors and investigators.

Statistical Aspects

Statistical methods play a role in study design as well as description and analysis of results. Statistical aspects to consider in a study include sample size, randomisation procedure, interim analysis as well as specific statistical models and methods.

Issues in analysis

Comparison of baseline characteristics of the randomised treatment and control groups is important, to ensure that balance was achieved. In analysing the benefit of the intervention being trialed, all subjects should be included, i.e. analysis is not restricted to those who have completed a course of treatment. Results of subgroup analyses need to be interpreted with care, as characteristics of subgroups may not be evenly distributed.

Sample Size and Power

Sample size calculations determine the number of subjects required to detect a treatment difference with specified levels of type I and II error protection. Power calculations determine the power associated with a specified treatment difference, given a specified sample size. Sample size and power calculations may lead to subsequent design modifications.

In a trial, statistical power is dependent on two factors:

- the number of endpoints experienced by the study population
- the difference in compliance between the study groups.

Ascertainment of outcome

Results should not be biased by the collection of more complete and accurate information from one or other of the study groups. Complete follow up of study subjects is required for the duration of the trial. To minimise the potential for observation bias, a trial can be conducted using blind or double blind procedures.

Good Clinical Research Practice (GCRP)

A standard by which clinical trials are designed, implemented and reported, ensuring the data are credible and the rights, integrity and confidentiality of the subjects are safeguarded.

Objectives

- Safeguard the interests of subjects, investigator, sponsor and society
- define the obligations of investigator, sponsor, ethics committee and national authority
- ensure that adequately planned and conducted clinical studies are performed
- facilitate timely and detailed quality assurance of study procedures
- minimise waste of human and financial resources
- inform those involved of the minimum requirements for a high quality study.

Role of National Authorities

The Therapeutic Goods Act 1989 and Therapeutic Goods Regulations form the legislative basis for the regulation of clinical trial activities in Australia.

Applications for clinical studies are reviewed by the Therapeutic Goods Administration (TGA) of the Commonwealth Department of Health, Housing and Community Services under the Clinical Trials Notification Scheme (CTN) or the Clinical Trial Exemption Scheme (CTX). Under the CTN scheme, clinical trials (usually early phase trials) are submitted directly to the Ethics Committee for assessment and approval. A clinical trial application to the CTX scheme is submitted to the TGA which has fifty days to respond to the submission.

Data Management

Data management converts information from the subject into data in the report, efficiently and without errors. All steps should be documented to allow retrospective assessment of data quality. Consistent terminology, codes and format assist with data processing, analysis and auditing.

Preservation of Records

The principal investigator and sponsor are obliged to retain all records, including computer, safety, audit and inspection data, subsequent to the study completion. The time frame is usually no less than 15 years from the date of termination of the study, and ideally should be for the life of the product under investigation.

Responsibilities of Sponsor and Investigator

The sponsor, usually a pharmaceutical company, individual, institution or organisation, initiates, organises and supports a clinical study of a product on human subjects. Areas of responsibility include:

- provide information and Indemnity
- prepare/agree to Protocol
- supply and monitor quality control for the product under investigation
- review serious adverse events
- conduct quality assurance and internal audit programmes.

The investigator and sponsor communicate via monitors, appointed by the sponsor.

Responsibilities of the monitor include review of case report forms, clinical trial supplies and other study related documents.

The investigator is involved in the design and/or conduct of a clinical study. Areas of responsibility include:

- agree to Protocol
- obtain ethics committee approval:
 - informed consent
 - protocol amendments
- safe handling, storage, dispensing and return of unused product
- data recording and archiving
- adverse event reporting.

Adverse events

An adverse event is an undesirable experience occurring to a subject during a clinical study, whether or not it is related to the product under investigation. The experience can range from minor to serious. The investigator and sponsor have particular responsibilities concerning the reporting of adverse events, clearly stated in the study protocol.

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HIV INFECTION IN SOUTH AUSTRALIA

HIV Infection 1985 - 30/06/97

There have been 666 individuals diagnosed with HIV infection, 617 (93%) males and 49 (7%) females. Of the males diagnosed, 470 (76%) reported male to male sexual contact, 54 (9%) reported injecting drug use and 27 (4%) reported both risk factors. Injecting drug use was reported by 22 (50%) of the women diagnosed with HIV infection and 20 (41%) reported heterosexual transmission.

HIV Infection 01/04/97 - 30/06/97

Of the nine men reported with HIV infection during the second quarter, 8 reported male to male sexual contact as their risk factor (Table 1.1). Between 01/01/97 and 30/06/97 five men (reporting male to male sexual contact) had acquired their infection in the preceding 12 months (Table 1.2).

Laboratory Screening For HIV Infection 01/04/97 - 30/06/97

During the second quarter of 1997 there have been 18,432 screening tests performed, 8,372 (45%) on males, 9,896 (54%) on females and 164 tests on individuals whose sex was unknown (Table 1.3).

**Table 1.1 HIV infection detected in South Australia in 1997.
New diagnosis of HIV infection, by sex and exposure category 01/04/97 - 30/06/97, cumulative to 30/06/97.**

Exposure Category	2nd Quarter 01/04/97 - 30/06/97		Cumulative 01/01/97 - 30/06/97	
	Male	Female	Male	Female
Homosexual contact	8		15	
Heterosexual contact	1	0	1	1
Unknown/other	0	0	0	1
Total	9	0	16	2

Table 1.2 HIV infection detected in South Australia in 1997. Testing history, by age at diagnosis of HIV infection 01/04/97 - 30/06/97, cumulative to 30/06/97.

Testing History	2nd Quarter 01/04/97 - 30/06/97			Cumulative 01/01/97 - 30/06/97			Total
	Age			Age			
	<25	25 - 39	40+	<25	25 - 39	40+	
No previous test	1	1	1	1	*2	*4	7
Previous 12 months	0	2	1	2	2	1	5
12 - 24 months	0	2	1	0	5	1	6
Total	1	5	3	3	9	6	18

* includes 1 female

Table 1.3 Number of HIV antibody tests performed in 1997, by laboratory and sex 01/04/97 - 30/06/97, cumulative to 30/06/97.

Lab	2nd Quarter 01/04/97 - 30/06/97			Cumulative 01/01/97 - 30/06/97			Total
	Male	Female	Unknown	Male	Female	Unknown	
Public	6402	7074	164	12785	14450	354	27589
Private	1970	2822	0	3618	5385	0	9003
Total	8372	9896	164	16403	19835	354	36592

HEPATITIS C SURVEILLANCE IN SOUTH AUSTRALIA

Hepatitis C Medical Notification 01/04/97 - 30/06/97

During the second quarter of 1997, laboratory notifications of positive hepatitis C antibody tests were received for 348 individuals. Of these, 324 (93%) were notified by medical practitioners. Among the 324 medical notifications, 118 (37%) cases were reported as never having a previous test, and 104 (32%) previously had a positive test for Hepatitis C antibodies. Thirty (9%) individuals previously had a negative test for hepatitis C and the testing history was unavailable in 72 (22%) cases. Of the 30 individuals with a previous negative test, 14 were incident cases, with negative serology in the preceding 12 months, or acute clinical illness (Table 2.3).

Among the 220 cases in whom antibodies to hepatitis C were detected for the first time in the second quarter, 158 (72%) reported past or present injecting drug use as a possible transmission route. In 11 (5%) cases, receipt of blood or blood products was reported, and in a further 11 (5%) tattoos were present, no exposure was identified in 22 (10%) cases (Table 2.1). The majority of males, (92%) were aged between 20 and 49 years; 63% of women were aged between 20 and 39 years (Table 2.2).

Hepatitis C antibody tests were performed on 7292 males and 7811 females, 79 tests were performed on individuals whose sex was not stated (Table 2.4).

Table 2.1 Medical notifications of cases with first positive hepatitis C antibody test in the period 01/04/97 - 30/06/97, cumulative to 30/06/97. Exposure category by sex.

Exposure Category	2nd Quarter 01/04/97 - 30/06/97		Cumulative 01/01/97 - 30/06/97		Total
	Male	Female	Male	Female	
IDU*	119	39	220	88	308
Blood transfusion/blood products	5	6	15	12	27
Tattoos	6	5	16	8	24
Other**	7	11	17	23	40
Unknown	19	3	49	17	66
Total	156	64	317	148	465

* includes IDU, IDU/tattoos, IDU/tattoos/blood transfusion and IDU/blood transfusion.

** includes exposure categories body piercing, residence in a high prevalence country, household contact, positive sexual partner, perinatal.

Table 2.2 Cases with first positive test for hepatitis C antibodies in the period 01/04/97 - 30/06/97, cumulative to 30/06/97. Age group by sex.

Age Group	2nd Quarter 01/04/97- 30/06/97		Cumulative 01/01/97 - 30/06/97		Total
	Male	Female	Male	Female	
Under 10	-	1	0	4	4
10 - 19	2	4	7	7	14
20 - 29	43	15	85	38	123
30 - 39	61	25	128	52	180
40 - 49	39	10	70	20	90
50+	11	9	27	27	54
Total	156	64	317	148	465

Table 2.3 Cases of hepatitis C infection acquired in the preceding 12 months, 01/04/97 - 30/06/97, cumulative to 30/06/97. Exposure category by sex.

Exposure Category	2nd Quarter 01/04/97 - 30/06/97		Cumulative 01/01/97 - 30/06/97		Total
	Male	Female	Male	Female	
IDU	10	2	20	4	24
Tattoos	0	1	0	1	1
Household	0	1	0	1	1
Unknown	0	0	1	0	1
Total	10	4	21	6	27

Table 2.4 Summary of laboratory screening for hepatitis C antibodies, by sex. 01/04/97 - 30/06/97, cumulative to 30/06/97.

Lab	2nd Quarter 01/04/97 - 30/06/97			Cumulative 01/01/97 - 30/06/97			Total
	Male	Female	Unknown	Male	Female	Unknown	
Public	4680	4227	79	9240	8342	234	17816
Private	2612	3584	0	5082	7027	0	12109
Total	7292	7811	79	14322	15369	234	29925

HEPATITIS B SURVEILLANCE IN SOUTH AUSTRALIA

Hepatitis B Medical Notification 01/04/97 - 30/06/97

During the second quarter of 1997, 89 hepatitis B medical notifications were received. Of these, 6 were acute clinical cases of hepatitis B infection (Tables 3.1, 3.2). A further 17 were reports of chronic carriers of greater than twelve months duration, who had been previously diagnosed but not notified and 66 were reports of antigen positivity of uncertain duration (Table 3.3).

Of the 66 reports of antigen positivity of uncertain duration, 29 tested surface antigen positive for the first time this quarter and the testing history was unknown for the remaining 37 cases. Among the 29 individuals who tested surface antigen positive for the first time, but were not acute cases, the racial origin of 14 (48%) was reported as Asian (Table 3.4).

The number of hepatitis B surface antigen tests performed by laboratories for this quarter is shown in Table 3.5.

Table 3.1 Acute cases of hepatitis B infection for the period 01/04/97 - 30/06/97, cumulative to 30/06/97. Risk category by sex.

Risk Category	2nd Quarter 01/04/97 - 30/06/97		Cumulative 01/01/97 - 30/06/97		Total
	Male	Female	Male	Female	
IDU	1	1	2	1	3
Heterosexual Contact	0	1	0	2	2
Social/Family	0	1	0	1	1
Unknown	1	1	3	1	4
Total	2	4	5	5	10

Table 3.2 Acute cases of hepatitis B infection for the period 01/04/97 - 30/06/97, cumulative to 30/06/97. Age group by sex.

Age Group	2nd Quarter 01/04/97 - 30/06/97		Cumulative 01/01/97 - 30/06/97		Total
	Male	Female	Male	Female	
20 - 29	1	1	1	2	3
30 - 39	1	1	3	1	4
50+	0	2	1	2	3
Total	2	4	5	5	10

Table 3.3 Hepatitis B infection for the period 01/04/97 - 30/06/97, cumulative to 30/06/97. Case category by sex.

Case Category	2nd Quarter 01/04/97 - 30/06/97				Cumulative 01/01/97 - 30/06/97		Total	
	Male		Female		Male	Female		
	No.	%	No.	%	No.	No.	No.	%
Acute Infection	2	4	4	11	5	5	10	6
Antigen positivity - uncertain duration	40	74	26	74	84	50	134	76
Chronic carriers - >12 months duration	12	22	5	14	23	10	33	18
Total	54		35		112	65	177	

Table 3.4 Individuals who tested hepatitis B surface antigen positive for the first time during the period 01/04/97 - 30/06/97, cumulative to 30/06/97. Race by sex.

Racial Origin	2nd Quarter 01/04/97- 30/06/97				Cumulative 01/01/97 - 30/06/97				Total	
	Male		Female		Male		Female			
	No.	%	No.	%	No.	%	No.	%	No.	%
Aboriginal	2	11	0	-	5	11	0	-	5	7
Asian	11	61	3	27	26	58	9	39	35	52
Caucasian	3	17	8	73	9	20	12	52	21	31
Other/Unknown	2	11	0	-	5	11	2	9	7	10
Total	18		11		45		23		68	

Table 3.5 Laboratory screening for hepatitis B surface antigen, by sex. 01/04/97 - 30/06/97, cumulative to 30/06/97.

Lab	2nd Quarter 01/04/97 - 30/06/97			Cumulative 01/01/97 - 30/06/97			Total
	Male	Female	Unknown	Male	Female	Unknown	
Public	4561	6239	94	9197	12797	257	22251
Private	2628	5083	0	4946	9916	0	14862
Total	7189	11322	94	14143	22713	257	37113

GENITAL CHLAMYDIAL INFECTION IN SOUTH AUSTRALIA

The STD Control Branch recently upgraded the chlamydia, gonorrhoea and syphilis notification systems. From September, 1997 notification forms for cases of these diseases will be posted, together with reply paid envelopes, to medical practitioners within South Australia. *To avoid duplication, please discard old blue and white Chlamydia /Gonorrhoea and Syphilis notification forms.*

Genital Chlamydial Infection 01/01/97 - 30/06/97

There were 595 cases of genital chlamydial infection notified between 1 January and 30 June 1997 (Table 4.1). Of these, 233 (39%) were male and 362 (61%) were female.

Genital Chlamydial Infection 01/04/97 - 30/06/97

Between 1 April and 30 June 1997, 329 cases of genital chlamydia were notified. Annual screening programs conducted during April and May in the aboriginal Anangu / Pitjantjatjara lands in the north-west of the state contributed to an increase in notifications during this quarter.

Of the 329 cases of genital chlamydia, 135 (41%) occurred in males and 194 (59%) in females (Table 4.1). In males, 104 (32%) cases were aged under 30; and 179 (55%) cases occurred in females aged less than 34 years (Table 4.1).

The number of genital chlamydia tests performed by South Australian laboratories during this quarter are shown in Table 4.2.

Table 4.1 Genital chlamydial infection in South Australia for the period 01/04/97 - 30/06/97, cumulative to 30/06/97. Age group by sex.

Age Group	2nd Quarter 01/04/97 - 30/06/97		Cumulative 01/01/97 - 30/06/97		Total
	Male	Female	Male	Female	
10 - 14	1	2	2	5	7
15 - 19	22	62	37	116	153
20 - 24	52	74	87	128	215
25 - 29	29	23	53	53	106
30 - 34	12	18	21	26	47
35 - 39	10	8	15	21	36
40+	7	7	15	13	28
Unknown	2	0	3	0	3
Total	135	194	233	362	595

Table 4.2 Laboratory testing for genital chlamydia in South Australia for the period 01/04/97 - 30/06/97, cumulative to 30/06/97.

Lab	2nd Quarter 01/04/97 - 30/06/97		Cumulative 01/01/97 - 30/06/97		Total
	Male	Female	Male	Female	
Public	1235	3049	2600	6257	8857
Private	630	2075	1214	4661	5875
Total	1865	5124	3814	10918	14732

GONOCOCCAL INFECTION IN SOUTH AUSTRALIA

Gonococcal Infection 01/01/97 - 30/06/97

There were 235 cases of gonococcal infection notified between 1st January and 30th June, 1997 (Table 5.1).

Gonococcal Infection 01/04/97 - 30/06/97

During the second quarter, 152 cases of gonorrhoea were reported to the STD Control Branch which represents an increase compared to the first quarter (83 cases). A high proportion (71%) of gonococcal infection was reported from the Anangu / Pitjantjatjara lands in the north-west of the state, where annual screening programs were conducted in April and May.

104 (68%) cases of gonococcal infection occurred in men, and 48 (32%) in women. Stratification by age shows 29 (60%) cases occurred in women aged less than 25 years, while infection in men was equally distributed. Ten (7%) of the 152 cases of gonorrhoea were reported as conjunctival infections.

Amongst the 104 men with a positive test, 26 (25%) reported male to male sexual contact. In males, 79% of gonococcal infections were acquired from sexual partners in South Australia.

Table 5.1 Gonococcal infection in South Australia for the period 01/04/97 - 30/06/97, cumulative to 30/06/97. Age group by sex.

Age Group	2nd Quarter 01/04/97 - 30/06/97		Cumulative 01/01/97 - 30/06/97		Total
	Male	Female	Male	Female	
< 15	2	1	2	3	5
15 - 19	20	18	23	25	48
20 - 24	20	10	34	23	57
25 - 29	28	7	37	10	47
30 - 34	10	6	22	11	33
35 - 39	10	1	15	5	20
40+	11	4	16	4	20
Unknown	3	1	4	1	5
Total	104	48	153	82	235

CLINIC 275 ACTIVITY REPORT

Table 6.1 Clinic 275 - Summary Statistics

Diagnosis	Period 01/04/97 - 30/06/97		Cumulative 01/01/97 - 30/06/97		
	Male	Female	Male	Female	Total
No illness	491	370	1005	759	1764
HIV	1	0	5	0	5
Gonorrhoea	21	1	39	3	42
Syphilis	1	0	2	0	2
Herpes	31	27	64	41	105
Chlamydia	28	19	61	41	102
NSU	39	0	66	0	66
Warts	205	55	406	132	538
Trichomoniasis	0	1	0	2	2
Candida vaginitis	0	91	0	186	186
Crabs	36	10	64	15	79
Scabies	11	0	17	0	17
Molluscum	19	7	48	14	62
Bacterial vaginosis	0	61	0	118	118
Acute hepatitis B	0	0	0	0	0
Hepatitis B antigen positive	2	1	4	1	5
Hepatitis C infection	22	6	33	13	46
Urethral irritation	51	0	113	0	113
Balanitis	51	0	90	0	90
Non STD illness	137	71	228	127	355
Post coital contraception	0	31	0	74	74
Abnormal Pap smear	0	53	0	95	95
Other/Uncertain	17	23	57	57	114
Clinic attendances	2204	1429	4510	2879	7389
Episodes of care	1076	723	2203	1484	3687
Individual clients	1022	689	2091	1419	3510

Note: A client may have more than one diagnosis for an episode of care. An individual client may have several episodes of care each requiring one or more attendances. Data on episodes of care and individual clients are from the computerised casenote system based on date of first visit for an episode of care. Clinic attendances were obtained from the daybook for the time period covered by this report.

Table 6.2 Number of men diagnosed with chlamydia, gonorrhoea or syphilis at C275, by exposure category, 01/04/97 - 30/06/97.

Exposure Category	Chlamydia	Gonorrhoea	Syphilis	Total
Homosexual	1	18	-	19
Heterosexual, IDU	6	-	-	6
Heterosexual, overseas contact	2	-	-	2
Heterosexual	19	1	1	21
Other/Unknown	0	2	0	2
Total	28	21	1	50

Table 6.3 Number of men diagnosed with hepatitis C, hepatitis B and HIV infection at C275, by exposure category, 01/04/97 - 30/06/97.

Exposure Category	Hepatitis C	Hepatitis B* Previous Exposure	Hepatitis B carrier	HIV	Total
Homosexual	0	10	0	1	11
Homosexual/IDU	2	0	0	0	2
Bisexual	0	1	0	0	1
Bisexual/IDU	1	2	0	0	3
Heterosexual, IDU	14	7	1	0	22
Heterosexual, overseas contact#	0	2	0	0	2
Heterosexual	3	8	1	0	12
Other/Unknown	2	1	0	0	3
Total	22	31	2	1	56

* No case of Acute hepatitis B diagnosed during reporting period.

* Previous exposure to hepatitis B refers to previous infection and now surface antibody positive.

Overseas contact in the previous three months

Table 6.4 Number of women diagnosed with hepatitis C, hepatitis B or HIV infection at C275, by exposure category, 01/04/97 - 30/06/97.

Exposure Category	Hepatitis C	Hepatitis B* Previous Exposure	Hepatitis B carrier	HIV	Total
Heterosexual, IDU	3	1	0	0	4
Heterosexual, overseas contact#	0	0	0	0	0
Heterosexual	1	8	1	0	10
Sex Worker	0	0	0	0	0
Sex Worker/IDU	1	1	0	0	2
Other/Unknown	1	0	0	0	1
Total	6	10	1	0	17

* No case of Acute hepatitis B diagnosed during reporting period.

* Previous exposure to hepatitis B refers to previous infection and now surface antibody positive.

Overseas contact in the previous three months

Clinical Trials at Clinic C275

1988 - 30/06/97

Gonorrhoea

Fleroxacin versus Spectinomycin in the treatment of uncomplicated gonococcal urethritis. 1988

HIV/AIDS

Low risk Zidovudine trial H56-020 1989 - 1992

ITR - INT49

The dynamics of the antiviral effect of AZT

M-331-0013 B Delavirdine trial

NUC B3007 3TC trial

OPAL - MRC ARNS Follow up study of AZT vs Placebo Cohort 1993

005 Delta trial 1994

Genital Herpes

Valaciclovir versus Acyclovir in the treatment of first episode genital herpes. 1993-94

Herpes Vaccine Prophylactic Study HSV007. 1995 -

Extended Follow up Phase of Study HSV007 1997 -

Herpes Vaccine Safety & Efficacy Study HSV017. 1996 -

Herpes Vaccine Safety Study HSV016. 1996 -

Famciclovir versus Valaciclovir in reducing lesional recurrences of HSV 2, following treatment of first episode genital herpes. 1996 -

An assessment of the Human & Economic Impact of Recurrent Genital Herpes infection. 1997

Hepatitis G Virus

Hepatitis G virus prevalence study 1997

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