AUSTRALIAN MILITARY FORCES

R980-500-47

Headquarters Australian Force VIETNAM

16 Oct 68

See Distribution List

AFV (AFMY COMPONENT) TRIAL INSTRUCTION NO 9/68 EFFECTIVENESS OF DAPSONE-PALUDRINE AS A MALARIA SUPPRESSANT

General

- 1. There is every good reason to believe that a drug called 'Dapsone', if taken in conjunction with Paludrine, gives added protection against malaria. It is strongly emphasised that Dapsone taken on its own will not give significant protection and that it must be taken in conjunction with another suppressant.
- 2. Dapsone has been used previously in conjunction with Quinine and Primaquine for the treatment of malaria, and the effectiveness of this treatment is well documented. This instruction describes the procedure for the evaluation of Dapsone and Paludrine when used together as a malaria suppressant.

Aim

3. To determine the effectiveness of Dapsone with Paludrine as a Falciparum malaria suppressant.

Trial Units

- 4. The following units are to conduct the trial:
 - a. 1 RAR
 - b. 9 RAR (on arrival in SVN)
 - c. 4 RAR (excluding V and W Coys)
 - d. 12 Fd Regt (excluding 161 Bty)

Trial Officers

5. Each of the trial units is to appoint a Unit Trial Officer, who is to supervise the conduct of the trial within his unit in accordance with this instruction. 1 ATF is to appoint a Trial Coordinating Officer, through whom Unit Trial Officers are to pass all results and questions relating to this trial to HQ AFV (FORS, Deer 273). 1 ATF is to signal the names of the Unit Trials Officers and Coordinating Officer to HQ AFV by 19 Oct 68.

Conduct of the Trial

- 6. Two platoons of each rifle company and one section of both field batteries are to receive one Dapsone tablet per man per day in addition to the normal two Paludrine tablets per man per day. The Dapsone tablet is to be taken by each member of the selected platoons and Artillery sections at the morning Paludrine parade.
- 7. The remaining elements of each rifle company and the remaining sections of the field batteries are to act as control to the trial. They are to take only the normal two Paludrine tablets per man per day.

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-2-

- 8. Daily records are to be kept by the Trial Officer, as per Armex A, showing the following information:
 - a. Platoon/gun section strength actually on Operations.
 - b. Platoon/gun section strength within 1 ATF perimeter.
 - c. Location of platoons/gun sections, and rifle company headquarters at 1800 hrs, when on operations.
- 9. The Coordinating Officer is to advise HQ AFV by 20 Oct 68 which platoons and gun sections are selected to use the Dapsone-Paludrine tablet combination.

Trial Period

10. The trial is to commence on 23 Oct 68 and continue for at least one month. Depending on the significance of the results, the number of operational days, and the areas in which the operations are conducted, it may be necessary to extend the trial period for a further one or two months, to ensure that the effectiveness of Dapsone-Paludrine is fully tested.

Trial Stores

11. Dapsone tablets are to be drawn by Unit Trial Officers from SMO 1 ATF.

Reports

12. A report on the significance of the results of the trial is to be issued by FORS, HQ AFV, one month after the start of the trial and at monthly intervals subsequent to this should the trial period be extended. The classification of the Trial Report is to be RESTRICTED.

Publicity

13. No publicity is to be given to this trial without the prior approval of HQ AFV.

(sgd) M. BRADBURY Colonel Chief of Staff

Annex: A. Daily Records

Distribution:

1 ATF (12)

For information:

AHQ (C) AHQ (M) HQ 1 ALSG 1 Aust Fd Hosp SMO 1 ATF HQ NZ V Force HQ RAAFV

Internal: FORS GS03 (SD and Trg) ADMS; ADPR; DADST

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ANNEX A TO AFY
TRIAL INSTRUCTION NO 9/68
DATED 16 OCT 68

DAILY RECORDS

Information Required

- The basic information which is required is:
 - a. How many men from the rifle companies and gun sections of the field batteries were outside the 1 ATF perimeter on operations each day, and where were the platoons, company headquarters and gun sections located at 1800 hrs on that day?
 - b. How many men from the same sub-units were at NUI DAT each day? This figure will include LOB personnel, dutymen etc remaining in camp when the sub-unit is out on operations, and when the sub-unit is in camp will include the strength of the sub-unit at morning parade.
- 2. For ease of control the above information is to be recorded each day and forwarded by CONFIDENTIAL signal as shown in the example signals included in this Annex, as Appendix 1, Battalion Daily Record; Appendix 2, Specimen Battalion Daily Record; and Appendix 3, Battery Daily Record.
- 3. The normal 1 Aust Fd Hosp reporting system will provide the information concerning number, rank, name, sub-unit and platoon or gun section of any of the members involved in the trial who contract Vivax or Falciparum malaria, or who are reported as having PUO.

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SCHEDULE OF RESULTS RECORDED CASES OF MALARIA

TRIAL	DATE	DAPSONE WITH PALUDRINE	PALUDRINE ONLY	REMAINDER 1 ATF(AUST)	NZ COMPONENT	REMARKS	
(a)	(b)	(c)	(d)	(e)	(f)	(g)	
1	23 Oct 68	2F	1F	5F, 1V	2F		
2	24 " "	1F	0	4F	1F, 2V		
3	25 " "	0	0	4F	0	During period 23 Oct 68 - 3	
4	26 " "	0	0	4F, 1V	0	Nov 68 there	
5	27 " "	1F	2F	2F, 1F+V	4F, 1V	were 76 cases (falciparum from	
6	28 " "	0	0	7F	2F	3 RAR which was	
7	29 " "	0	0	18F, 1V	3F, 1V	not included in the trial	
8	30 " "	1F	1V	13F, 1V 1F+V	5F		
9	31 " "	0	1F	10F	11F, 1V		
10	1 Nov 68	0	1F+V	7F	7F		
11	2 " "	0	0	10F	9F		
12	3 " "	1F	1F+M	7F	9F	and	
13	4 " "	0	3F	1F	5F	85% probability figure for	
14	5 " "	0	1F	2F	3F,2F+V	falciparum	
15	6 " "	1V	0	1F	9F, 2V	incubation is 12 to 16 days	
16	7 " "	1F	0	1F	7F		
17	8 " "	0	3F	4F	8F	Scrutiny period of trial begins	
18	9 " "	0	3F	3F	3F		
19	10 " "	0	1F	2F	4F		
20	11 " "	0	4F	0	3F		
21	12 " "	0	5F	1F	2F		
22	13 " "	0	1F	3F	5F		
23	14 " "	0	2F	9F,1F+V	3F		
24	15 " "	0	3F 1V+F	1F	4F		
25	16 " "	0	1F.	4F İ	_ 4F		
26	17 " "	0	1F	1F	2F		
27	18 " "	0	0.	1F	2F, 1F+V	All 1 ATF	
28	19 " "	0	0	1F	1V	commenced	
29	20 " "	0	0	0	0	taking Dapsone	
30	21 " "	0	2F	1F	0		

(a)		(ь)	(c)	(a)	(e)	(f)	(g)
31	22		, ,,	0	0	0	10	
32	23	,	1 11	0	0	0	0	(5)
33	24	,		0	1F	0	0	
34	25	,	2 22	0	0	1F		
35	26		1 11	0	0	0	0	
36	27	,	т н	0	0	1F	0	
37	28		11	0	0	0	0	
38	29	11		0	1F+V		0	
39	30	**	n	0	1V	0	0	
40	1	De	c 68	0	0	17		Cpl Y. See para
41	2	"		0	0	0	1F,	
42	3	"	"	0	0	0	1:0	
43	4	11	11	0	0	0	0	16 days since all
44	5	11	"	0	0	0	0	1 ATF began takir Dapsone
45	6	11	11	0	0	0	0	Dapsone
46	7	11	11	0	0	0	0	
47	8	**	"	0	(1)	0	0	See para 14. Type of malaria not known. Pte X
48	9	11	н	0	0	0	0	
49	10	11	н	,0	0	0	0	
50	11	"		0	0	0	0	
51	12	11	"	0	0	0	0	
52	13	"		0	0	0	0	
53	14	"	"	0	0	0	0	
54	15	11	11	0	0	0	0	
55	16	11	n	0	0	0	0	
56	17	"	"	0	0	0	0	
57	18	"	"	0	0	0	0	
58	19	11	11	(1F)	0	0	0	Previous history,
59	20	11	11	0	0	0	0	see para 14 Lopl Z
50	21	n	11	0	0	0	0	
51	22	11	11	0	0	0	0	
52	23	11	"	ю	0	0	0	
3	24	**	"	0	0	0	0	
4	25	11	11	0	0	0	0	
5	26	11	11	0	0	0	0	The second
6	27	11	11	0	0	0	0	
7	28	**	11	0	0	0	0	

(a)	(b)	(c)	(å)	(e)	(f) [(g)
68	29 " "	0	0	0	0	
69 T	30 " " OTALS	0	0	0	0	
17-41	8 Nov 68 - 2 Dec 68	0	27F,2F+V,1V	34F,1F+V	41F, 2V, 1F+V	
42-69	3 Dec 68 - 30 Dec 68	10	0	0	0	

NOTES:

- F falciparum; V vivax; F+V falciparum with vivax;
 F+M falciparum with malariae.
- 2. The movements of trial units and 3 RAH during and immediately before the trial period are as follows:
 - a. 102 Fd Bty was at NUI DAT until 27 Oct 68 and at FSPB LION (YS 6181) from 28 Oct 68 until the end of the trial period, 16 Nov 68.
 - b. 104 Fd Bty was at FSPB FLINDERS (YS 5289), for the duration of the trial.
 - c. 1 RAR was on operations in AO PENRITH, centre of mass YS 3289, until 11 Oct 68 and at NUI DAT from 12 Oct 68 to 27 Oct 68, with the exception of one company which was at FSPB WILTON (YS 5476), during 21-26 Oct 68. 1 RAR then moved to AO WATSON, centre of mass YS 6284, on 28 Oct 68.
 - d. 3 RAR was in AO DICKSON, centre of mass YS 5889, from 12 Oct 68 and returned to NUI DAT on 22 Oct 68. 3 RAR less two companies was in AO EVERGLADE, centre of mass YS 2477, from 25 Oct 68 to 2 Nov 68, and then returned to NUI DAT. Platoons of 3 RAR undertook minor operations in the TAOR until 3 RAR was relieved by 9 RAR on 20 Nov 68.
 - e. 4 RAR was at NUI DAT until 12 Oct 68, and then in AO DICKSON during 13-29 Oct 68.

- The subjects should be volunteers either healthy persons or patients for whom the experimental design is not related to the patient's illness.
- The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.

as recovered with a medically quadrand person and as all asset on the services as

 In research on man, the interest of science and society should never take precedence over considerations related to the wellbeing of the subject.

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I. BASIC PRINCIPLES

- Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.
- The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.
- Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.
- Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
- Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interest of science and society.
- 6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
- Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.
- In publication of the results of his or her research, the physician is obliged to
 preserve the accuracy of the results. Reports of experimentation not in
 accordance with the principles laid down in this Declaration should not be
 accepted for publication.
- In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.
- 10. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to

NUI DAT

DAPSONE TRIAL 1ATF

Herewith details of members of 1ATF who commenced taking DAPSONE 1 daily from

(a)	1RAR				
(b)	4RAR	A Coy E Coy C Coy D Coy	1 4 7 10	Pl Pl Pl Pl	2 Pl 5 Pl 8 Pl 11 Pl
(0)	12 500	B Coy C Coy D Coy	5 8 10	Pl Pl Pl	6 Pl 9 Pl 11 Pl

12 FD Gegt

217101

215284

- nominal roll of members taking DAPSONE and PALUDRINE. This roll represents approximately 50% of each Fd Bty(AUST). PALUDRINE twice daily only.

(i) 102 Fd Bty RAA (in alphabetical order)

235307 Lt AHEARN I.F. 3791286 Gnr AYSON G.T. 2788595 Cnr DATKER A.W. Ludr BIRD L.W. 216065 111615 Gnr BROWNE T.C. 18110 Pdr BURNS J.L. 140492 Gnr BURROWS G.J. 53222 Sagt BUSHBY R.W. 2786950 Gnr B CKHOUSE K. 43910 Pte CARRUTH J.D. 15439 Sgt CLENDINEN A.W. 2786551 Gnr COLLIER W.J. 22093 W02 COX A.R. 31311 Sgt COSTELLO P.W. 2788656 Gnr CRANNA R.G. 6410240 Gnr CURRAN R.J. 2784739 Bdr DARRAGH R. C. 2785765 Gnr DOYLE J.M. 1731589 Lbdr EASTON J.F. 2786623 Gnr FORD J.S. 3410998 Sgt FRANKLIN M.J. 4719292 Gnr GOOD A.J. 2786358 Gnr HAHN J. 6708941 Gnr HART.R.J. 2412512 Gnr HERMANN J.F. 5715271 Gnr HODGE G.J. 217062 Gnr HOGAN. R.E. 2787430 Gnr1 JARRETT M.J. 2788767 JOTHSON W.F. Gnr 43130 ...ING A.J. 3411891 Bd: LANG D. R. 6708869 Gnr LECONARD F.J. 2786180 Gnr LYNCH J.A. 2183805 McDCCLD D.P. Gnr 5715120 Gnr MICKEOWN S.T. Gnr MCHURRAY 39053 MORRIS B.C. Gnr 2787519 Gnr NEWELL R.J. Lbdr OLSEN B. A. 3791476 3793007 Gnr FARKINSON R.D. 1733041 Gnr RICITIONED H.C. 1411329 Gnr ROBINSON E.W. 3790503 Gnr RYAN J.P.

Lbdr SCHWARZE J.E.

STEFHENS L.J.

Sat

1. Copies to:

a. A-D

b. RAD

C- Each MO

d. Med wand.

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102 Fd Bty RAA (cont.)

3791391 Gnr SITH R.M. 2784949 Lbdr TWOMEY B.J. 15559 Capt TAIT D.M. 3411360 Bdr WAFREN I.H.

(ii) 104 Fd Bty RAA

5715603 Gnr ADAMS L.P. 1200594 Lbdr HEASLEY R.J. WO2 HENNETT-BURLEICH J. 310360 2787242 Cnr : BOWYER J.C. BYRON E.S. 2786201 2Lt BROOKER R.C. 44004 Gnr CANE R.A. 2788643 Gnr 2788630 Gnr CARTER B.J. 3791859 Pte CHARTER M.G. 2789198 Gnr COLLINS G.J. Gnr FLOYD G.J. 39488 GUEST T.P. 217795 Gnr HAACK G.F. 15556 Sgt HAMPTON E.B. 1410578 Sgt IVERS M.G. 2787778 Gnr JOHNSTON F.J. 3791957 Gnr ZLt KENDALL V.T. 18717 3792046 Gnr MACKENZIE R.J. Bdr He DOWELL B.J. 29303 2786723 Cnr M/HER B.J. QUATERMASS E.J. 214070 SGt 2783870 Gnr PRIZEMAN D.J. ROBINSON K.A. 55266 Gnr 2787580 Gnr RUTKOWSKI J. Lbd. RUTHERFORD L.A. 38909 4719371 Gnr SCHWARZ K.G. Capt SHAMP P.K. 235245 4719832 Gnr STEPHENS K.A. SHIPARD R.J. 5411662 Gnr SMALL P.G. 2787605 Gnr STONE L.J. 1733119 Gnr 2787877 Gnr THOMAS D. TIDYMAN B.J. 216046 Gnr 28738 Sgt TILEROOK P. VERKUYLEN P. 3411186 Bdz WOTTON K.J. 2787673 Gnr

> (W.B. JAMES) Maj. SMO 1ATF

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MESSAGE FORM

PRECEDENCE - ACTION PRECEDENCE - INFO | DATE-THAE GROUP MESSAGE INSTRUCTIONS ROUTINE | DEFERRED | 2700, 2 | DEC 68

FROM AUSTFORCE VIETNAM | SECURITY CLASSITY CLASSI

ANTI MALARIALS . WHEN MEMBERS EBGIN THEIR 14 DAY COURSE OF CHLOROQUINE
AND PRIMAQUINE PREPARATORY TO RTA THEY ARE TO CEASE TAKING DAPSONE . AN
AMERIMENT TO AFV (ARMY COMPONENT) HO NO 126/68 MAY BE ANTICIPATED

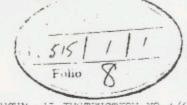
INFO:

Page 1 of 1	Classified NO	Drafters Name	Office	Tele No
		NYMAN	DAAG	244
		Releasing Off	icor's Signatu	
				- Mai

HQ AFV 22 Nov 67

R515-1-1

List G (loss ser 8-16)



AFV MEDICAL TECHN AL THISTHUCTION NO

MANAGES NT OF MALARIA

- Reference: A. DGMS Technical bisvruction No 3/67.
 B. MBI 142-10 Andt No 1.
 d. DES 4036/3/2 dated 15 Nov 67.

 - D. AFV Mod 19215 dated 6 Pov .
 - E. AFV Med 19618 dated 10 Nov.

Aim

The aim of this instruction is to collate the above instructions 1. on management of malaria in this thouters.

General

- Under no circumstances is ralaria to be treated other than in accordance with reference A.
- If it is considered that local conditions require a variation of these instructions SMO AAFV is to be informed in order that DGMS may be -otified of any variation required.

Special Points in Managemen

- Blood transfusion should be given only rarely and then in conjunction with the clinical picture, A ND of 70 alone is not an indication for blood transfusion.
- Note para 6 of reference A. The primaquine course is not to be given to patients in a malmrlous area, except in accordance with MBI 142-10 para 35. Primaquine ten given, is taken in divided doses because even 14 mgm will cause some people to be nauseated.
- It " , NOT be assumed what all cases of malaria in Viotnam are falciparum malaria resistant to chlaroquine. US observers and other competent sources are finding more and more vivax. The incidence of vivax parasites amongst the localpopulation is 30% and there must surely be some vivax infections amongst Australian troops, as vivax is occurring in troops returned to Australia from Viotnam.
- Strict adherence to the instruction will prevent all cases of malaria being automatically treated with intra snous quinine and dapsone. In some areas in Vietnam it has been noted that quite a nuber of texic drugs are being used in concert and units savers bone marrow depression is being encountered.

Hetification

- All blood slides must be kept and followed through. They are to be forwarded to SMO AAFV in accordance with reference B.
- As soon as diagnosis of malacia is confirmed it is to be notified in accordance with reference E.
- All other instructions and writings except the references listed are to be cancelled and d stroyed.

SHO AAFV

From Lt Col R N HURLIY



AMEN FALL
APPOST

J GPO SYLEY Y

NEW

3 Dec 68

Lt Col II A NAUGRION CO 2 Mil Hosp INGL BURN NSW.Aust.

Pleased to hear from you and to get some insight into where the entimelarial system is breaking down.

From inventigations carried out here, there is no doubt that all medevace begin antirelarials except those where it is Medically contraindicated.

The problem is one of documentation and pro ten I will ensure that not only is the full regime written on the treatment sheets but also on the discharge summaries.

charts together with the anticularial charts.

Having discussed this with GiO RAF we feel that BTTOR ORDER document recur.

Prophylexis has changed. At the moment the region is Paludrine 1 BD plus Daprone 25 mgm daily. It appears as if it may be more effective.

We are treating all LT melaria here as chloroquine resistant and hence were using

Quinine for 10 days Darapin for 3 days and Daysono for 28 days

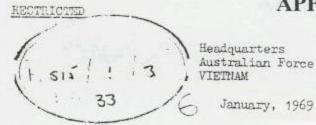
until the dapsone was added to the prophylactic regioe. Prophylactics ere continued during the course of therapy. I gather from our correct on principulae that ou are treating then with elderoquine/principulae regioe.

I have put up a suggestion that we don't start antimologicals for modevecs and honce they would all arrive at your place meeding to be in their course.

An in this way, people who have been placed on a redovace ANE I feel will send this to ANE no it won't be starting for a while yet at loast.

The hospital is being rebuilt fast and in 2 months I

R980-500-47



See Distribution List

FINAL REPORT ON AFV (ARMY COMPONENT) TRIAL NO 9/68 EFFECTIVENESS OF DAPSONE-PALUDRINE AS A MALARIA SUPPRESSANT

In Oct 68, following a severe and prolonged outbreak of malaria in 1 ATF, approval was given by AHQ for a field trial to determine the effectiveness of Dapsone-Paludrine as a malaria suppressant. The final report of the trial, which was conducted in Phuoc Tuy Province from 23 Oct 68 to 16 Nov 68, is attached. The report also includes further observations made during the period 17 Nov 68 to 30 Dec 68.

2. The trial showed that:

In Phuoc Tuy Province, at least, Paludrine alone is of diminished effectiveness as a chemoprophylactic agent against falciparum malaria.

The addition of 25 mg daily of Dapsone to the normal 200 mg (100 mg per tablet) daily dosage of Paludrine resulted in the effective suppression of all forms of malaria in 1 ATF.

With effect from 17 Nov 68, a regime of 25 mg Dapsone and 200 mg Paludrine daily was adopted as the standard anti-malarial chemoprophylactic in AFV (Army Component). Mowever, it is recommended that research be conducted into the long term effects of this regime, particularly with regard to any toxic effect on the individual and the possibility of a Dapsone-Paluarine resistent strain of Talciparum malaria emerging.

> (A.L. MacDONALD) Major General

Commander Australian Force

VIETNAM

Enclosure: 1. Final Report

Distribution:

AHQ (C) AHQ (M)

For information:

1 ATF 14 1 ALSG (14)AATTV (2) HQ RAAF V HQ NZ V Force (3)

Internal: C of S Files 980-500-47 GS02 (SD & Trg) GS02 (FORS) 506-1-17 DAAG Spare (10) ADMS DADST NSO (2)

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AUSTRALIAN ARCHIVES

ITEM: 1 of 1

Series/ Accession number :: AWM100

Series/ Accession number :: AWM100 Item Number :: R515/1/3 Item title :: 1 Australian Field Hospital - Medical Diseases -

Malaria (Note: Includes Final Report on

Dapsone Trial)

Item date range :: Circa 1900 1
Access decision :: NONE
:: Not yet examined :: circa 1965-1972 circa

Availability : RECORDED AS MISSING - JAN 1997

Availability

Location :: AWM Database accession number :: 884544

*** END OF PRINTOUT FILE ***

Australian Hillitary Paraga DDMS Office, Headquarters, Eastern Command, Victoria Barracks, PADDINGTON. N.S.W.

3 W 92/16 51001

20th July, 1966. Was a rest of the contract of

AGF/HJ

506/E1/9(Ned)

Col. R.H. Black, School of Public Health and Tropical Medicine, University of Sydney, Sydney, N.S.7.

AFFINALARIALS AND HEAF TOLERANCE

- "A" Branch has sought the necessary volunteers from a number of units with suitable personnel. It is not possible to provide them at the present time.
- It is thought that members of 1 RAR should be available about December, 1966. This unit has been in SOUTH VIETHAL but they will have been home six months then.
- The major exercise in Sept. -Oct. is causing a great deal of troop movement which makes it difficult to get people at the intervals required.

Col. (A.G. FIREJY) DDMS E Comd.

9

DECLARATION OF HELSINKI

Recommendations guiding physicians in biomedical research involving human subjects

Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964 amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975 35th World Medical Assembly, Venice, Italy, October 1983, and the 41st World Medical Assembly, Hong Kong, September 1989.

Introduction / I.Basic Principles / II.Medical Research Combined with Medical Care / III.

Non-Therapeutic Biomedical Research

INTRODUCTION

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfilment of this mission.

The Declaration of Geneva of the World Medical Association binds the physician with the words:

"The health of my patient will be my first consideration", and the International Code of Medical Ethics declares that "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.