UNCONFIRMED MINUTES

Document 86/5

ROYAL COLLEGE OF PHYSICIANS

A meeting of the College Sub-Committee on the Ethics of Epidemiological Studies was held at the College on Wednesday 10 September 1986 at 2.30 pm.

Present

Sir Douglas Black	Chairman
Sir Richard Doll	
Dr B L Priestley	
Dr D A Pyke	Registrar
Mrs Janet R Richards	
The Rt Hon Sir Kenneth Robinson	
Dr J H Tripp	
Dr N Wald	

In attendance

Dr T W Meade	
Mr D B Lloyd	Secretary Elect
Miss Pamela Nash	Committee Secretary

1 Apologies for absence

Apologies were received from:

Sir Raymond Hoffenberg	President
Dr M Bobrow	
Dr R F Mahler	
Dr P J Taylor	
Mr G M G Tibbs	Secretary

Sir Douglas welcomed Dr Wald, the representative from the Faculty of Community Medicine to the meeting. Mr Lloyd was introduced to the meeting as the Secretary Elect.

A welcome was extended to Dr T W Meade.

2 To receive a list of the members of the Committee (Document EP86/1) Action

The list of members of the Sub-Committee was accepted and the Chairman thanked members for agreeing to serve.

3 The role of the Committee (Document EP86/2)

Sir Douglas commenced by telling the Committee that this meeting had been called as a result of a letter received from Dr Betty Priestley (Doc EP86/2) following the last meeting of the Committee on Ethical Issues in Medicine held on 25 March 1986. The letter had been prompted by the discussion which had centred on the screening of people for AIDS without their knowledge that this was being done and the concern which a number of the Committee had expressed after the meeting, about uninvited medical intervention in a variety of different spheres.

This had been followed by a letter from Dr Meade which had focussed on a specific problem rather than the subject in general. Dr Meade had therefore been invited along to discuss this matter (item 4 of the agenda) after the general discussion on the role of the Committee.

Dr Betty Priestley told the Committee that in the informal chat following the meeting Drs Bobrow, Mahler, Tripp and herself felt that various concerns arose from the question of uninvited medical intervention and/or the provision of unsolicited information following population screening. These included:-

1 The person involved may not want to know.

2 The question of confidentiality arises if the condition affects others, but the patient does not want the information divulged. How far should disclosure go - close family, extended family, work, general responsibility to the community? Is there a duty to trace? Is there a case of negligence if attempts to trace relatives are not made? What about disruption to members of families who may not want the information?

3 Dr Priestley pointed out that in her specialty screening has shown that an increasing number of conditions can be discovered both pre- and neo-natally. What should happen if a condition is discovered? Does one hand the information onto people who have not asked for it? There is also the problem of accidental detection. If a condition should be disclosed it may adversely affect the following months of pregnancy and ultimately the relationship between mother and baby and that in itself raises further issues.

4 Finally it had been felt that there were also the problems raised by population screening for pre-symptomatic disorders and carriers.

Sir Richard Doll advised the Committee that the general issue involved a distinction between research procedures and procedures which formed a part of normal service activities the latter in particular involving vast problems.

With regard to research procedures the position has not changed in 30 years - the views held in 1950 still being valid - uninvited intervention results should be used for research only. Information, however serious, should not be disclosed if permission to do so has not been obtained. With regard to the specific case of AIDS it has been felt that if blood is taken in the course of service work with a view to finding out whether a patient has the infection then the patient must be told what the blood is to be tested for. If however you want to find, in the public interest, whether the AIDS infection is spreading through society then it is necessary to test blood collected for other purposes. It would be wrong to tell someone that they had AIDS if they had not given permission for the test to be done. Therefore the correct ethical approach is to test blood collected for other purposes which can be unidentified and the test results therefore cannot be communicated to those involved. This has been the approach generally adopted for research over the last 35 years or so and it is hoped this attitude will prevail. Sir Richard Doll summed up by saying that the essential thing in any research or study is to have accurate figures and so generally speaking unidentified samples should be used. Experience has shown that a specific request for urine/blood to be tested for a particular infection results in false figures and therefore conclusions as those most likely to be at risk are those most likely to refuse to take part. In fact there was clear evidence that people do not co-operate if there is any chance of later identification. Generally

speaking therefore it was agreed that for many purposes the guidelines used with regard to research do not need reviewing.

At this point it was felt that 3 issues had become apparent:-

1 the rights of the individual

2 research results

3 having obtained information which is important to both the individual and society can a justification be made for not using the information for the good of society

It was also agreed that the situation changes completely once a cure is available as in the case of TB, and that it is correct to distinguish between the curable and the presently incurable. Consideration was also given to the point that a person may alter his/her actions if they know they are infected and from this follows the need for counselling.

4 Consent for Trial of Anticoagulants (Document EP86/3)

Dr Meade drew attention to an issue raised by a trial of Warfarin in the prevention of heart attacks in those known to be at high risk. There was a tension between the duty of informing patients fully of risks which were probably small and uncertain; and the possibility of causing unjustifiable alarm, for which there was no real basis.

There were two reasons for the trial:-

1 Studies of data showing the use of Warfarin in the secondary prevention of fatal and non-fatal reinfarction show a 50% success rate in stopping further attacks.

2 Work over the past 15 years has established a strong relationship between the clotting function in blood at high levels (Factor 7) and the liklihood of a heart attack in the next few years. Factor 7 is affected by Warfarin and it is easier to lower the level of Factor 7 by adjusting the dosage of Warfarin rather than lowering the cholesterol level. If the relationship between F7 activity and heart attacks can be reversed then it is possible that the prevention of heart attacks can be achieved by reducing the activity level at the lower end of the normal range.

The trial had been approved by at least 10 ethical committees.

Dr Meade reported that the risks are discussed with the patients but the extent to which discussion goes rests on various legal and ethical aspects.

The legal side rests on the Siddaway case in which it had ultimately been decided that explanation of risks need not extend to covering extremely rare possibilities. Therefore there rests a responsibility to discuss possible risks but not necessarily remote possibilities, but this allows leeway for discretion. The MRC was consulted and their decision in this case had been that the GP should be advised of the hazards and it is then their responsibility to use the information in their discussions with the individual involved, bearing in mind their knowledge of the patients' personality.

In this trial, the procedure was that a selection of men were asked to undergo a series of tests from which the top 15-20% of those at risk of having a heart attack were chosen. These men were then tested further, discussed matters with their GP and given the leaflet (Doc EP86/3) to consider before having a full medical examination and further opportunity to discuss what was in the leaflet. Therefore there is about 4-6 weeks between the patient being told that they are at risk, and their entry to the trial, thus allowing plenty of time to discuss and consider the trial before agreeing to any involvement.

Dr Meade continued by saying that those involved in the trial are asked to complete a questionnaire every two months. This included 5 questions concerning bleeding, minor episodes of bleeding, nose bleed, red or pink urine, easy bruising and passage of blood in stools. The answers have been identical from those taking Warfarin and those taking the control drug. At no time has there been any question of making no reference to bleeding or not giving full details to those requesting them. There has always been an attempt to strike the balance between giving as much information as possible to a person probably in a highly anxious state and not giving enough information particularly about the possibility of bleeding. This essentially is why the procedure of letting the GP discuss the trial with the patient has been adopted since he knows the personality of the patient. The doctor discusses the possible good or bad effects, and the fact that a patient can come off the trial at any time.

It was agreed that Dr Meade had managed to achieve a correct balance in making information available to the patient.

Sir Douglas thanked Dr Meade for attending the meeting and giving an instance of a specific trial involving the very ethical issues under discussion.

5 Any Other Business

There was no other business

6 Date of Next Meeting

Although no date was set for a future meeting, it was agreed that a report should be taken back to the main Committee after which a decision would be made whether the Sub-Committee should meet again and if so when. It was generally agreed that the meeting had been a useful one.