10 DOWNING STREET

THE PRIME MINISTER

18 September 1983

Dear Mr. Longmore,

I am writing to thank you very warmly for your letter of 14 September and for the fascinating papers which you attached to it.

I was able to draw on your note about the organisation of health care in a talk which I had with Norman Fowler on Friday. Both he and I share your view that the nub of the problem is to get more of the money we devote to the Health Service spent effectively on patient care and much less spent on administration. And under the heading of spending the money effectively, I also agree with you that we must take full advantage of the opportunities of prevention which developments like the nuclear magnetic resonance machine provide. I gather that you have no objection to my showing Norman Fowler your paper privately, and I shall do that.

I agree that this is an area of major political importance, and I am very grateful to you for your help in setting down your diagnosis and your prescription so clearly.

I have just written to Arnold Weinstock urging him to bring forward the appointment to see you.

Yours sincerely

Margaret Thatcher

Donald Longmore, Esq.

Lord Weinstock
Letter to D-L re Health
the Sunday Post if possible
MF

4

PRIME MINISTER

You may like to read over the weekend Donald Longmore's letter and his paper on the NHS. You do not need to read all the enclosures.

In my view, the diagnosis in Donald Longmore's paper is better than the prescription on the National Health Service, which looks rather naive. But the criticisms ring true, and there is no mistaking the sense of frustration with all the bureacracy, which runs through his paper.

Donald Longmore told me that he would have no objection to your showing his paper to Norman Fowler, and, if you agree, I will do that, asking Norman Fowler to keep it personal to himself, Kenneth Clarke and Ken Stowe.

Another aspect on which you may like to take action is the letter of 5 August to Lord Weinstock's personal physician about the risk that GEC will miss the opportunities provided by the NMR. I gather that Donald Longmore has asked for an appointment with Arnold Weinstock but has not been able to get one until November. You might consider telephoning Lord Weinstock and telling him that you have met Donald Longmore and perhaps urge him to see Longmore and Dr. Ian Young a bit sooner: it would not do you any harm for you to be urging Lord Weinstock to do something for once rather than the other way round!

Finally I attach an acknowledgement to Donald Longmore for your signature. If you telephone Lord Weinstock over the weekend, you may like to add a sentence on the lines:

"I have already spoken to Arnold Weinstock about the NMR and have urged him to see you as soon as possible and take seriously what you say about it."

F.E.R.B.

16 September 1983

DEPARTMENT OF CLINICAL PHYSIOLOGY

NATIONAL HEART HOSPITAL

MR. DONALD LONGMORE

WESTMORELAND STREET, LONDON W1M 8BA
TELEPHONE 01-486 0824
01-486 4811

Our Ref.

Your Ref.

14th September, 1983

The Rt. Hon. Margaret H. Thatcher,
10 Downing Street,
London S.W.1

Dear Prime Minister.

As requested by you during our recent enjoyable visit to Dunphail, I am sending you a number of documents which may be of interest. I was concerned about boring you with too many medical matters and too much discussion about the Health Service and the future of medicine at what was clearly intended to be a relaxing weekend for you. However, as someone working in the field I feel that the Health Service presents much bigger and more immediate problems than is generally appreciated. There is an impending crisis.

As you will see from the enclosed papers, I am worried that the biggest foreseeable hazard facing you relates to the Health Service, as we discussed under various headings.

Hector invited me to meet you because I was one of the founder members of CORDA (Coronary Artery Disease Research Association), a national charity of which he is an enthusiastic patron. CORDA is dedicated to changing our approach to cardiovascular disease from the present costly notion of salvaging people with end-state symptomatic disease, to that of prevention. Since occlusive vascular disease (blocked arteries) accounts for approximately half of all deaths and probably more than half of all the incapacity, the elimination of this disease will have enormous social implications. It will probably extend the normal life span by only a few years, but by enabling the elderly to stay fit enough to contribute to society and to look after themselves, it could eliminate the drudgery of old age. For this reason

we have studied the age-population structure and examined some aspects of the relationship between those who are generating our national wealth and those who are consuming it. This is why we touched on the retirement age in our discussions and why the properly annotated graph is enclosed.

Flag A

We have recently finished a book (in press) for CORDA which argues in detail the case for a change in the approach to the treatment of cardiovascular disease. A copy will be sent to you as soon as it is published. In the meantime, in the next week or two, I will send you a copy of the typescript and illustrations of the introductory chapter which covers the most important points.

Whereas a few years ago the idea of preventing cardiovascular disease would have been merely theoretical, two major advances now make it a practical possibility:

1. N.M.R. (nuclear magnetic resonance) when used to its full potential will be ideal for early diagnosis.

2. Arising from John Vane's Nobel Prize winning discovery of prostacyclin (a substance which prevents blood clotting within us), recent discoveries relating to the genesis of atheroma.

These two major developments have placed within our grasp the necessary prerequisites for the conquest of the disease, namely accurate early detection and effective treatment before it becomes serious.

We discussed N.M.R. briefly and I mentioned to you my concern about British industry's role. Most of the innovations which have made N.M.R. imaging practicable are British. Notable amongst them have been the efforts of Nottingham University, regrettably damaged by mismanagement of the cuts in spending at the University which has closed most of its physics department yet kept the department of Hebrew studies. Fortunately, Professor Peter Mansfield, the first man to produce a human image, following it with movie N.M.R. pictures, has remained in this country. Due to the efforts of Sir Godfrey Houndsfield who won his Nobel Prize along with Cormack for producing the mathematics which made image reconstruction possible, part of E.M.I. (later taken over by G.E.C.) produced the only really satisfactory working

machine. This is now at the Hammersmith Hospital. Lord Weinstock, I think wisely, has purchased an American X-ray company in order to market this device in the U.S.A. but is experiencing the usual problems encountered when the Brtish try to get something done in the U.S.A. I am concerned that he is at risk of letting this hugely profitable section of British industry, the biggest prize ever in medical engineering, slip from his grasp. A few weeks ago Dr. Louis Freedman (Lord Weinstock's personal physician) discussed the matter with me, as a result of which I wrote to him (a copy of this letter I enclose in confidence). It sets out my understanding of the position. I am hoping shortly to meet Lord Weinstock and Dr. Ian Young (the brains behind the new generation of equipment) in order to try to set this situation aright.

flag B

About ten years ago I tried to set up an association of British companies involved in medical engineering. It was disappointing to see that one by one the firms concerned either failed, were nationalized, or allowed their internecine struggles and inefficiencies to delay their progress and thus let the Americans and Japanese overtake them. Virtually all we have left is the N.M.R. project. If this fails we may as well abandon hope for the British medical industry. Enclosed is an article written in 1969 when I was becoming concerned about this inadequacy and when I was trying to set up some kind of concerted British effort. In this context, it was wonderful to hear that you have broken the monopoly of the British Technology Group. Its existence has caused me and other inventors of medical equipment a great deal of grief; most of our ideas have been developed abroad. The existence of N.R.D.C., later B.T.G., has meant that if they have not supported an idea no-one else was prepared to look at it.

flag C

CORDA was originally chaired by Robert Carr (one of its founder members), who saw the need for a change in the emphasis in medicine and who has put in an enormous amount of time and effort, resulting in an excellent organisation and a powerful group of patrons. It was under the guidance and chairmanship of Mr. Cyril Roberts that CORDA began its active campaign. The charity is now chaired by Cecil Clothier (the Ombudsman) who sees very clearly the opportunities presented by Dr. Young's conception of second generation N.M.R., and understands both the national and medical implications of the

British development of this mainly British technology. It is my hope that when CORDA has funded basic N.M.R. research it will move on to support the more important plan of the mobile diagnostic units, about which a paper is enclosed. The worldwide export potential for these units, based on a British vehicle, British instrumentation, British training and British expertise is enormous. The markets encompass Europe, wealthy countries like Saudi Arabia and developing countries which are leap-frogging the present costly approach; curative rather than preventive medicine. It is my ambition to make this work before they screw the lid on my box!

Turning away now from the affairs of CORDA to the main substance of our discussion, the document concerning the National Health Service describes the situation as I see it, not from any political standpoint. It is a genuine, concerned attempt to save the government from what I see to be a very major crisis which will arise sooner rather than later. It has always surprised me that Dr. David Owen (to whom I once taught surgery and who has an intimate knowledge of the deficiencies of the Health Service) has not yet been clever enough to see that a combination of a swing to the right and an attack on the present management of the Health Service could enormously strengthen his political position. I do not believe that the Health Service can be saved in its present form, because the Department is now so big and powerful (yet irrelevant) that it can no longer be pruned sufficiently to leave a viable Health Service.

immediately below

Nye Bevan said:

> "The new Health Service has been having a most uneasy gestation and a very turbulent birth, but all prodigies behave like that ....."

I would like to see you gain the credit for the birth of a new and effective second generation health care scheme.

Please remember that if I can help in any way I will do what I can.

With all good wishes to you and Denis.

Yours sincerely,

Donald Longmore,

Donald B. Longmore, FRCSEd
Consultant Clinical Physiologist

encs.

THE CREATION OF A PROPER HEALTH CARE SYSTEM BY THE CONSERVATIVE GOVERNMENT IN 1984

This document deals with the urgent need for a re-structuring of the health care system in the U.K. It discusses the alternatives of the abandonment of the Health Service, trying to re-vitalise the existing Service, and outlines a new scheme which is satisfactory both to the needs of the country and of the Conservative Government.

In addition to the unforseeable hazards of political accidents and international events, the Government is at risk from entirely predictable sources.

The general public will tolerate many things provided that they are seen to be beyond anybody's control. Thus turmoil in the Middle East, Africa and Central America; unease about the similarity between the acquisitive behaviour of Moscow and the military ambitions of Nazi Germany; the bizarre behaviour of extreme right and left and the world economic situation, are accepted. The public are opportunistic about the inefficiencies of the tax and social security systems and regrettably corruption has become part of life. Even mistakes are forgiven provided they are seen to be genuine.

Should blame be assignable to the government of the day, however, their tolerance disappears; that the problem has been developing for decades will not be taken into account. The informed public accept the realities of the economic situation and the need to control inflation, as clearly demonstrated by the general election results. They are not, however, prepared to be neglected or exploited when they are genuinely ill. Sooner or later the advent of sickness and the inadequacies of health care affect every family. The apparent neglect of the Health Service is slowly but surely creating massive discontent.

The key factor in maintaining confidence in the Government amongst the general public is its integrity as a custodian of the health services, making them available to any who should really need them. They must not appear unconcerned, nor should they. All tribes, societies and civilisations have been forced to adopt some communal approach to health care, sometimes using it as a means of exerting influence. The Christian churches lost influence coincidental with the secular take-over of medicine, hospitals, the care of old people, and schools. Apparently Nye Bevan was conscious of the political influence of health care and used it to advantage:

> "Society becomes more wholesome, more serene and spiritually healthier, if it knows that its citizens have at the back of their consciousness the knoweldge that not only themselves, but all their fellows, have access, when ill, to the best that medical skill can provide."

The National Health Service presents particular problems to any government trying to be responsible in the field of health care. Many believe that the demands of medicine will always grow and could never be met. Certainly the responsibilities of the Health Service includes very disparate fields, from geriatrics to intensive care, from chronic psychiatric disease to accident surgery. Unfortunately, the mass media, encouraged by some

medical practitioners, have led the public to believe that certain very glamorous and very expensive fields such as open heart surgery represent the growing edge of medical progress. Confidence in what can be done increases, with it grows expectation of better performance from the health services. This has the twin effects of increasing demands to unrealistic levels and diverting funds from unglamorous areas, which if neglected, generate social problems on a scale large enough to topple a government.

The Government could turn this unpromising situation to its advantage by being seen to be sponsoring a realistic and cost-effective system which tackles the more relevant but less glamorous problems (see Appendix 1 - the medical need for mobile cardiovascular diagnostic units).

At present, with the emphasis on cost ineffective and largely unsatisfactory management of advanced disease, the level of dissatisfaction with medical care in the U.K. is higher than in any other country practising similar medicine, or spending only a slightly larger proportion of its national wealth on health. In 1979 the U.K. spent 5.4%, U.S.A. 9%, W. Germany 5.7%, Holland 8.6%, Italy 6.3% (1976), Denmark 7.4%. Norway 7.6%, France 7.2%, Japan 4.4%, Switzerland 6.9% (1977), Australia 7.6%; the average excluding the U.K. is 7.1%. The difference lies only partly in our lower expenditure and the increased expectation of health care in a country with a health service. The real problem is the cost-ineffectiveness of the organisation of medicine, including its present uncomfortable relationship with the social security system. In the countries listed, virtually all of the 7.1% of the Gross National Product is spent on patient-related activities. Here, a large proportion of the lesser sum is wasted.

There is no historic reason why a Conservative government could not solve the problem quickly. The Labour party is still allowed to take the credit for the inception of the Health Service. Nye Bevan is revered for turning the nation's post-war dream into legislation, against the opposition of the medical profession, within the span of one government. In reality the scheme for a high standard of health care for all was the natural outcome of the organisation of medicine in war-time Britain and Beveridge in Churchill's Coalition Government. Some of the more comprehensive recommendations came in 1943 from Henry Willink, a Conservative M.P. The Labour party do not have a historical monopoly for health care. The unions are conspicuously absent in the lists of donors to medical research, in the creation of health centres in deprived areas, in supporting old peoples homes etc. When CORDA (see Appendix 2) was founded it was a Conservative ex-Cabinet minister , not a Socialist, who was prepared to devote months of spare time to hard work to create the charity.

It cannot be said that the faults of the present system were not anticipated by the public and by the medical profession. In 1943 the Ministry of Information commissioned Mass Observation to survey public attitudes towards a National Health Service. There was widespread enthusiasm for the principle but fear of a more bureaucratized service. Throughout, the British Medical Association expressed fears of interference from bureaucrats "entirely ignorant of medical matters". As it has transpired, it is not so much interference that has damaged the National Health Service, it is the less tangible existence of a huge bureaucracy skilful enough to avoid interference or even performing any identifiable function which could be commented on or criticised.

There are three possible courses of action:

1. To abandon the Health Service by total immediate privatisation or by neglect.

2. To continue to prop up the present inefficient system at enormous cost.

3. To start again with a new and cost-effective health care system with the intrinsic faults of the existing system eliminated.

For the following reasons only the third option is viable.

A case could be made for the Health Service to be abandoned, arguing that it is unique to the U.K. and inspite of our great pride in it, no other country has tried to imitate it because it is not viable. No government could withstand the outcry which would follow an attempt to abandon the Service by immediate privatisation. Although the expanding private sector <u>appears</u> to be making a success of certain sections of medical care, closer inspection shows that this is not true overall. Only lucrative areas such as short-stay surgical care are being taken over and even here the private sector is failing to pull its weight, using Health Service laboratory facilities, providing no after-care and funding no research. No attempt is made by the private sector to tackle such long-term problems as senile dementia, epilepsy, Parkinson's disease or terminal care. A totally privatised system would thus provide a distorted service with fragmented endeavour and very poor response to social needs or government policy. Further unworkability would arise from a lack of machinery to deal with patients who needed care from more than one company or who due to error, or to unusual presentation of an illness, had gone to the wrong company.

An alternative is abandonment by neglect. For a number of years, successive governments appear to those dedicated to making the Health Service work, to be covertly eliminating the Health Service and not just ignoring it due to preoccupation with other pressing issues.

Inefficiencies and waste have been allowed to continue to debilitate the system so that it cannot even compete with the private sector in the management of short-term illnesses. If we liken the Health Service to a firm, it is retaining its high overheads which result from out of date buildings, equipment, working practices and chronic under investment. It also continues to carry a massive, very unwieldy and largely irrelevant administration. It has also lost important revenue from abroad, not only in charges for competitively priced medical care of a high standard, but also in hotel accommodation and other spending by relatives. This failure to cope with readily treatable disease increasingly leaves the taxpayer responsible for only the expensive, difficult and unsatisfactory areas of medicine. Any savings resulting from attempting to trim down the existing system will be disproportionately small.

Since abandonment of the Health Service is not a practical alternative, can the country afford to retain the Service either as it is or in a modified form? Given a huge amount of money, a powerful minister and a large slice of luck, an ideological optimist might consider this to be possible. There are, however, now so many factors and factions working against the Service in its present structure that even increasing the investment to an unrealistic 10% of the Gross National Product would only delay the collapse.

It would be easy to catalogue the complaints about the present system. The media and medical writers, the unions, doctors, nurses, and everyone whether involved or not, has an opinion about the root cause of the troubles in the Service. These are not reiterated in this document; a few examples are given illustrating problems at several levels.

If a region or a hospital is asked to economise the first step is to sack say 1,500 nurses and to close wards. This increases waiting lists and the frustration of those who are trying to work, further harming the image of the Government. Much greater savings could be made by eliminating the administrative waste. An example will illustrate the point:

Open heart surgery to bypass blocked coronary arteries is now the commonest operation in the U.S.A. The trend is similar here both in the Health Service and in the private sector. Although the surgical results are good, there is a very high

incidence of diffuse brain damage (see Appendix 3 - Lancet leader). The causes of this are many, but important are the toxic substances released into the patient's blood-stream from the tubing and the sterilising agents. The majority of imported equipment used for oxygenation of the patient's blood is made of polyvinyl chloride using phthalate plasticisers, and sterilised by ethylene oxide poison gas; both have F.D.A. approval (see Appendix 4 - Unsafe Regulation). This is in spite of the fact that it is well known that many foods cannot be stored in P.V.C. because toxic phthalates leach out into them; that most countries do not allow blood to be stored in P.V.C. bags, and that there have been frequent reports of phthalates in the blood of renal dialysis patients.

It is now also common knowledge that ethylene oxide is an unsatisfactory sterilising agent because its residues poison the patients. Yet the D.H.S.S. have steadfastly refused to listen to an advisory group of surgeons and physiologists who have explained to them both in committee and in private, the issues involved. The Department has preferred to set up a voluntary system of inspecting and licensing manufacturers in the U.K. and abroad, which produce this kind of equipment. Equipment made out of very dangerous materials and sterilised in a risky way, is condoned by inspection. When tackled about this the Department's response is that it cannot dictate to doctors what equipment they should use; it has no power to ban materials, and no mechanism for changing sterilising techniques. If this is the case, why exist at all? Even worse, why appoint further costly bureaucrats to inspect manufacturers, when the only results of this can be the demise of the remnant of the British medical industry and the exploitation of the system by foreign manfacturers who often use cheap home labour to assemble equipment, neatly avoiding tax and reducing labour costs.

The very office and officers which are facing us in this and other respects cost very substantially more than the 1,500 nurses they will sack to save money. A giant irrelevant organisation is strangling medicine by siphoning off an unacceptable proportion of the money devoted to health care and by creating long and unnecessary delays. Attempts to throw back the administration of health care into the local community have also failed, deflected by this organisation. Meanwhile, practising doctors are frequently faced with the scandalous situation of sitting on committees to decide whether patient 'A' or patient 'B' should be murdered by neglect because of the inadequate facilities. The committees sit in administrative blocks well insulated from the reality of the problems of patients 'A' and 'B'.

Bureaucratic torpor turns simple tasks into mammoth endeavours. If there is a dripping drain, no longer can we go to the basement of the hospital and ask the engineer to fix it, we have to approach the hosptial engineer through his secretary. After a decent interval we are allowed to go to see him to explain the problem. He then reports to the secretary of the group engineer who after a further delay will ask for resources from the area engineer. After it comes up in committee, we will probably be told that there is not enough money to devote to mending dripping drains in 1983. The whole system has become one of self-perpetuating administration. Health care no longer comes into consideration.

Every new area of endeavour is efficiently responded to by the Department by the creation of suitable divisions. Some years ago when we wanted to apply for computers in medicine, we found that a new building had been leased because there was no longer room in the two blocks at the Elephant & Castle or the Supplies Division in Russell Square. The new building in Holborn housed a number of C.R. (Computer Research) divisions. After a year's negotiations with C.R.5 it was made clear that if we wanted computers we would have to buy and maintain them ourselves. We suggested that the Computer Research Divisions might actually like to work on the computers, evaluating them in parallel with us. This was met with incredulity.

Bureaucracy is not only a problem in the hospital service. In North West Kent, an administrator has recently reprimanded the nurse in charge of diabetic patients and a dietician who wished to hold a function in their own time, at their own expense and in their own home, to enable the parents of diabetic children to pool resources and help each other in the management of this difficult problem. They were told not to become involved with their patients. The same administration still insists on the use of glass syringes at much greater cost than disposable plastic ones. In the same area, in common with most of the country, parents of diabetic children are expected to buy their own diabetic monitors, costing about £100 to the patient whereas they can be bought in bulk for about £60. The improvement in the management of the patients using this equipment reduces overall costs. This is further evidence of remote adminsitration handicapping the workers in the field and unnecessarily reducing the standard of patient care.

The examples quoted, all true, are those furthest removed from music hall farce. Even figures published by the D.H.S.S. itself have a whimsical air. The Health Service Manpower Summary for 30th September 1980 shows that in England at that time 43,725 medical practitioners were served by 105,430 administrative and clerical staff. 26,503 people were employed in the Works

Departments and there were 61,893 professional and technical employees. It is hard to believe that for every doctor employed, 2.4 administrative/clerical, 1.4 professional/technical and 0.6 works staff were needed. In this age of computers and operations research, 14,554 ambulancemen/women were supervised by 3,214 ambulance officers/control assistants, i.e. each officer supervised only 4.5 ambulancemen. The message is quite plain. Further injection of funds into the existing Health Service will not solve its problems. Asking the present D.H.S.S. to economise will result only in further damage to the image of the government because vital services will be closed down whilst those areas which need to be pruned will survive.

In spite of the high staffing levels at the D.H.S.S., controls seem not to work. Taking the building of new hospitals for example, my hospital was built with the post-mortem room directly above the kitchens so that leaks in the floor had disasterous consequences. It was also built of inferior materials and the ceilings fell causing a partial closure of the hospital for many months; that happened in the 1960s. About a decade later the facing materials at the new Cardiff Hospital began to fall off. A decade later still the new block at the Great Ormond Street Hospital which cost several million pounds, could not be opened because it had major structural faults. Surely this is evidence of a combination of poor control and failing to learn from experience.

The planning for hospitals and new facilities is also unsatisfactory. For a long time the Department had a policy of phasing building programmes for new hospitals. Phase 1 gets built, often not to be followed by successive phases. Thus in North London we have a hospital consisting of mainly old buildings plus a new phase one, which consists of a superb laundry capable of serving the new hospital which will probably never be built. There is obviously no official in the Department of Health, or group of officials, who are actively trying to damage the Service, the system in which they work seems to to make it impossible for reasonable people to do a good job. The system whereby no one person actually makes a decision and which makes it impossible for us, the consumers, to actually find somebody responsible means that mistakes can be repeated and no one appears to be accountable. At the individual level, there seems responsibility without authority, collectively there is authority without responsibility.

The current state of the National Health Service makes one wonder why it has not collapsed before. The answer lies in the dedication of the people who actually work in the hospitals, in practices and who have patient contact. They try to make the system work in spite of all the obstacles.

Throughout the Service there are doctors and nurses working unreasonably long hours attempting to cope with the clinical load, never stopping to question why they are so overworked.

Any new system intended to look after the nation's health alone must capitalise on this goodwill and demonstrate to the bona fide health workers a committment to urgent reform.

The proposal is that a new British Health Corporation should be set up. This should be chaired by someone renowned for getting things done (like Hector Laing). The new Corporation would be controlled by a very small board of management. It would consist of one government representative, one general practitioner, one representative of the ancillary services, one consultant, one scientist and one lawyer.

Its brief would be simple; to provide the best possible health care for the community operating within financial constraints which would ultimately be set at 5% of the Gross National Product and subject to review, upwards only to bring it into line with the rest of the Western world. In its constitution would be prohibited sub-committees, quangos, general purpose and finance committees etc., and any other committee structures which would grow to undermine the authority of the Board. This new organisation would inherit the freehold of all premises owned at present by the D.H.S.S., including hospitals but excluding the headquarter buildings at Elephant & Castle, Russell Square, Holborn and the very large number of administrative blocks scattered throughout the country as district and area authorities. The new board will be responsible for the salaries of certain categories of staff in the new health care scheme, including doctors, nurses, diagnostic technicians, radiographers, physiotherapists, occupational therapists, rehabilitation workers etc., and for the salary of one clerk per hospital. Each hospital would have a small allowance, limited by statute, to pay for administrative services. Each would be enabled to run its clinical services by electing its own medical superintendent (who would be spared for a short period from clinical duties each day) and the chief nursing officer as the matron and a hospital secretary or clerk to get on with the day to day running of medical practice. The new board would not be responsible for any of the salaries in the Central Department of the D.H.S.S., areas or the districts. Group practices and single-handed medical practitioners, would not be affected in any way.

The total sum available for Health would be divided into two; one part would be handed to the new authority for patient care, and the other part would be the cost in salaries and overheads of the existing Health Service administration. This would make a clear distinction between that part of the nations wealth which is spent properly on patient care and that part which is spent totally on irrelevancies. Over a three year period of transition, the new board would have the option of taking from the old D.H.S.S. structure any part of it which they considered useful, up to a maximum of say 10%, a figure written into the constitution. A financial disincentive to over-recruitment would be included, by making the board find 25% of the salary and overheads of any D.H.S.S. staff taken on.

During the three year period of transition, the existing D.H.S.S. would from the beginning take no active part in the management of health care. It would be instructed only to co-operate with the new board if asked for help. This would regularise the existing situation whereby a major proportion of the funding intended for health care is actually spent on matters which are valueless. It would lay the ground for the general public to see that an identifiable institution contributed nothing to health care but consumed a substantial proportion of its budget. The hospitals and local communities would be encouraged to ask for a larger share of the money allocated to health, and this would have to come out of the funds being used to support the old D.H.S.S. This shifts any unpopularity for redundancies and running down the old D.H.S.S. administration from Government to popular demand.

The board of the British Health Corporation service would be advised directly by representatives from the various medical associations and the unions, and by the universities. It would retain a small central office which would have computer links to the 2,000 or so existing health service hospitals which will be under its charge. Statistical information and other data about any hospital would thus be directly and immediately available to the board. Each hospital would interface with the community through a board of governors, under a chairman nominated by the board, approved by the Prime Minister. The governors would typically comprise a local magistrate, a teacher, a general practitioner, a hospital consultant, and an elected representative of the local council.

At the end of the three year period the corporation would review progress. Those parts of the present administrative section of the D.H.S.S. which would be clearly seen to be redundant would be eliminated. The buildings would be sold or converted into hospitals. From that time on, the whole of the 5% or more of the G.N.P. devoted to health care would be spent on just that. The appointment of the chairman of the British Health Corporation should be the responsibility of the Prime Minister of the day, advised by the Cabinet, but certain constitutional constraints would apply to ensure effective management.

The creation of a new health service is not a scheme which can be dealt with piece-meal, nor would a completely new plan readily survive the normal processes of prolonged debate distortion by the media and the onslaught of the traditional opponents of whatever a Conservative government is trying to do. The truth is an unimportant commodity in contemporary debate. For some reason, the general public are aware of any differences of opinion in Cabinet, and our excessive media are always hungry for any opportunity to fill their pages and their screens with unseemly debate. Perhaps some method should be sought to deal with this problem on a higher plane than is usual about routine government matters. The first question always asked by the media following any debate is "What is your reaction to .....?" This is a telling question for the media react to and distort events. They are able to drive a London bus through the eye of a political needle. In the case of something as important as the Health Service, would it not be possible to recruit the aid of the media in a unique way to deal with a unique problem, that of getting value for money from our health care system.

September 1983

This is a copy of a draft document which is currently being prepared for submission to a British company for support.

"Of no distemper, of no blast he died,
But fell like autumn-fruit that mellowed long,
Ev'n wondered at because he dropp'd no sooner.
Fate seemed to wind him up for fourscore years
Yet freely ran he on ten winters more;
'Till, like a clock worn out with eating time,
The weary wheels of life at last stood still."

Dryden 1678

The goal of every doctor and all who are interested in health care should be the universal achievement of a full life span, unsullied by disease and untarnished by dementia in old age.

SUMMARY OF THE BACKGROUND AND PRINCIPLES OF THE MOBILE DIAGNOSTIC UNIT

Until recently cardiovascular disease causing just over half of all deaths and immense morbidity has been undetectable in its early stages. No treatment of occlusive vascular disease was envisaged. Contemporary medicine attempts to ameliorate the effects of end state disease and endeavours to establish risk factors for occlusive vascular disease. Presently we have to wait a generation to see if any preventive concepts actually work.

In any science, medicine included, from time to time there are advances, often the ability to measure a new parameter, which make quantum leaps possible. Just such advances are becoming available in medicine now. Non-invasive cardio-diagnostic techniques, hitherto relatively weak, now include N.M.R. This promises to measure dynamically and precisely all the anatomical and physiological parameters necessary for diagnosing occlusive vascular (and many other) conditions. Used in combination with certain of the existing non-invasive diagnostic modalities, detection of occlusive vascular disease will shortly be available at an earlier stage than has hitherto been dreamed of, even in the invasive laboratory.

It would be meddlesome, however, to detect vascular disease in the community at an early stage were we not within sight of offering treatment rather than advice. Furthermore the advice we give our patients is not accepted; the currency of preventive advice is debased by unseemly debate between the proponents of possible irrelevancies such as margarine versus butter, to jog or not, to exercise, alcohol in moderation etc.

Following the discovery of prostacyclin, there has developed a new understanding of the genesis of atheroma. The role of the blood platelet in atheroma formation and the response of the vessel wall to adherent blood platelet have suggested new promising lines of research into the control of the platelet and of vessel wall response.

The two important coincidental advances of diagnostic ability and therapeutic possibility herald a new era in the management of cardiovascular disease. Within a decade the unacceptable reduction in quality and duration of life and financial burden on the insured community should be reduced.

For over five years the mobile diagnostic unit has been planned in order to detect occlusive vascular disease at its earliest stages. To achieve this, several prerequisites are necessary:

1. The diagnostic instruments must be non-invasive, cause no distress, yet be accurate and powerful, not producing a high incidence of false-positive tests. The non-invasive tests must reach far further back into the development of the disease than can the exercise ECG.

2. The tests must be taken to the "at risk" community and repeated regularly. Only by doing this can the natural history of the disease be studied. More importantly, the efficacy of preventive measures can be monitored (as shown in fig. 1 in section 1.1 of the main document).

It is proposed that the relevant diagnostic instruments, including the new generation N.M.R. machine, should be combined in the form of mobile diagnostic units which can be taken to factories, schools etc. in order to screen repeatedly the population within them.

3. In order to promote public awareness of the problem, the mobile diagnostic units will also be designed to carry educational video films describing the functioning of the unit, telling what is known about occlusive vascular disease and its avoidance. Facilities for demonstrating the immediate harmful effects of cigarettes will be incorporated.

Although the patient interface and the tests as far as the patient is concerned will be simple, the units will contain the most advanced instrument and computer technology available. The mobile diagnostic unit will produce data in several forms:

1. In the form of single patient records stored magnetically and interchangeable from M.D.U. to M.D.U.

2. Encoded magnetic cards which the patients can take to any M.D.U. to access their records.

3. In a main-frame computer store which can be retained for analysis and research.

The mobile diagnostic units will be self-financing by charging a fee to patients or workplace. A national chainstore and a major clearing bank have expressed an interest in cardiovascular screening using the M.D.U. facilities.

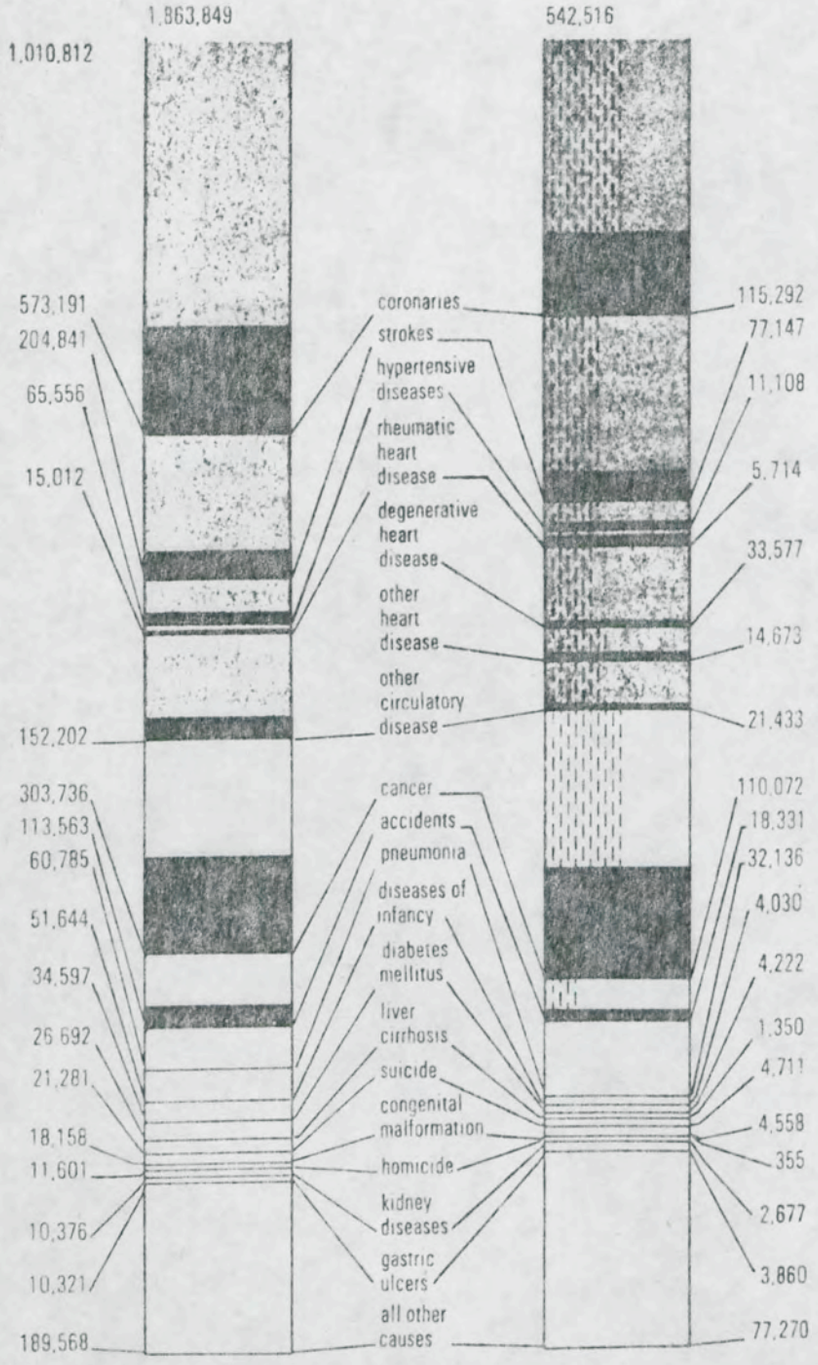
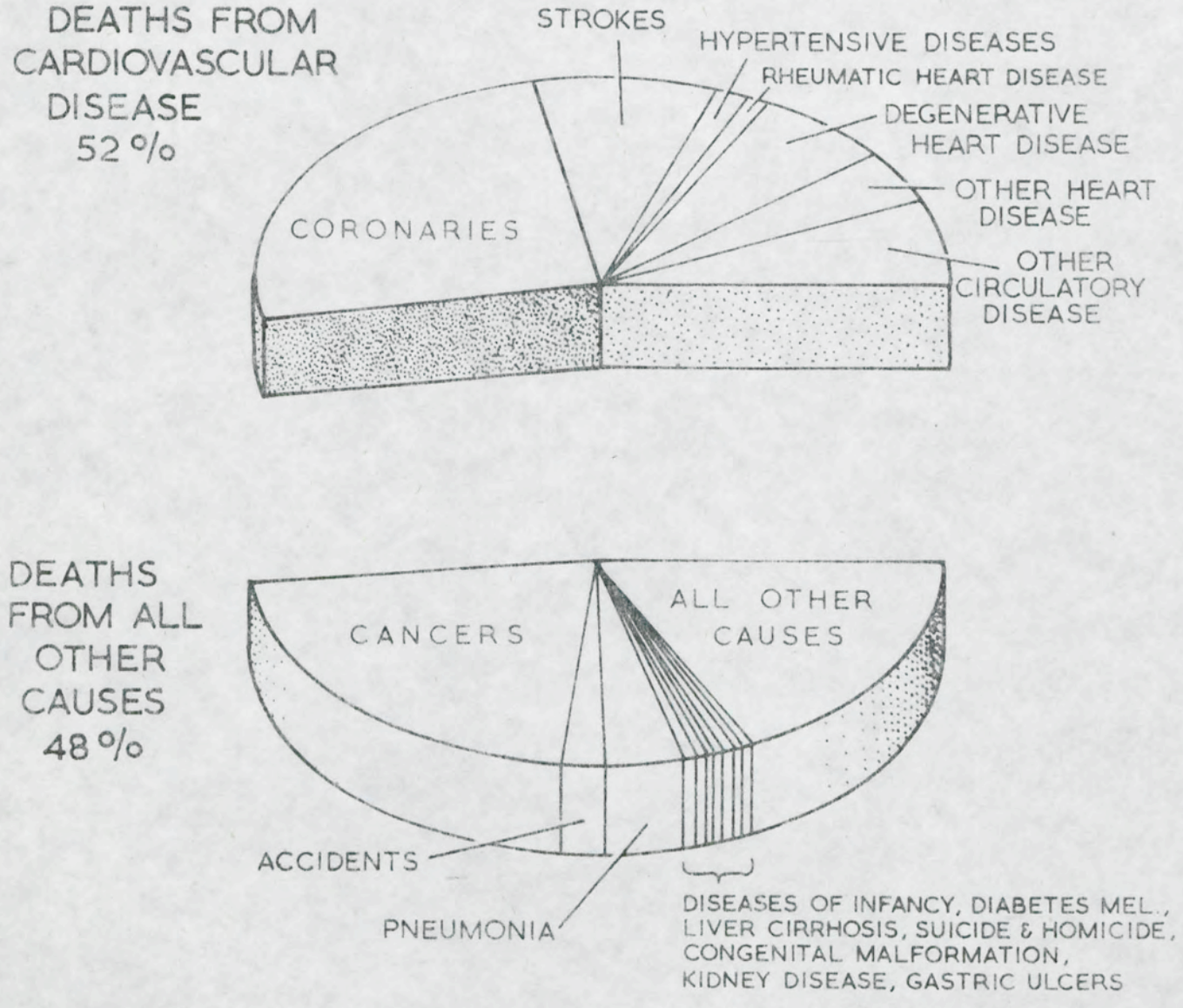


FIGURE 1a and 1b

These charts compare cardio-vascular disease (shaded) and other causes of death in the USA (left) and England & Wales (right). The figures are typical. Instead of averaging many years, I have picked 1966 (USA) and 1967 (E&W) as representative. Both histogra are reduced to the same height of comparison. With the exception of homicide, suicide and liver cirrhosis the figure are almost identical in the 2 countries. For some diseases, deaths in the working age grou are shaded grey, and the proportion of males is shown b stippling. This highlights th coronary deaths in the working male population.

Fig. 1b emphasises the relationship between the incidence of cardiovascular disease and cancer.

FIG. 1b


DEATHS FROM CARDIOVASCULAR DISEASE 52%
STROKES
HYPERTENSIVE DISEASES
RHEUMATIC HEART DISEASE
DEGENERATIVE HEART DISEASE
OTHER HEART DISEASE
CORONARIES
OTHER CIRCULATORY DISEASE
DEATHS FROM ALL OTHER CAUSES 48%
CANCERS
ALL OTHER CAUSES
ACCIDENTS
PNEUMONIA
DISEASES OF INFANCY, DIABETES MEL., LIVER CIRRHOSIS, SUICIDE & HOMICIDE, CONGENITAL MALFORMATION, KIDNEY DISEASE, GASTRIC ULCERS

THE ROLE OF THE MOBILE DIAGNOSTIC UNIT IN CARDIOVASCULAR DISEASE

S E C T I O N 1 (Part 1)

Background: The medical need for an M.D.U.

1.1 CARDIOVASCULAR DISEASE AND THE COMMUNITY

In the Western world, cardiovascular disease accounts for just over half of all deaths (fig. 1). Note that coronary and stroke, caused by occlusive vascular disease, are responsible for the most deaths (followed by cancer* (see footnote)).

1.2 The mortality from occlusive vascular disease is readily quantified. The morbidity caused by this disease process is enormous, making it so universal that it is accepted as a part of everyday life.

Occlusive vascular disease is probably avoidable.

An unfortunate family with young children might have two grandmothers incapable of coherent thought due to diffuse occlusive vascular disease. Both grandfathers and father have died as a result of a coronary attack and the mother is incapacitated due to a stroke.

The consequences of occlusive vascular disease are not often so extreme in any one family, but it is rare for a family to escape the disease. The social consequences are universal. In addition to the pain and suffering of individuals, the cost to the community is significant. An adult who dies of a coronary is typically a male in the prime of life. His contribution to the Gross National Product stops and his family may become a burden on insurance funds and the State. The calculated cost to the community in 1973 was £8,135,000,000

1.3 The insiduous nature of the disease is such that whilst it is well recognised that it affects an individual progressively over many years, it only becomes apparent that that individual is affected late in its course. Therefore contemporary medicine tends to intervene when "end state disease" is established. Conventional medical therapy and cardiac surgery try to treat symptoms and extend life in those already suffering from advanced occlusive vascular disease. Even the best attempts at detecting the disease process early such as the exercise ECG only detect well-established disease.

* The mobile diangostic unit is primarily designed to detect cardiovascular disease. It has the capability to detect some cancers at an early stage.

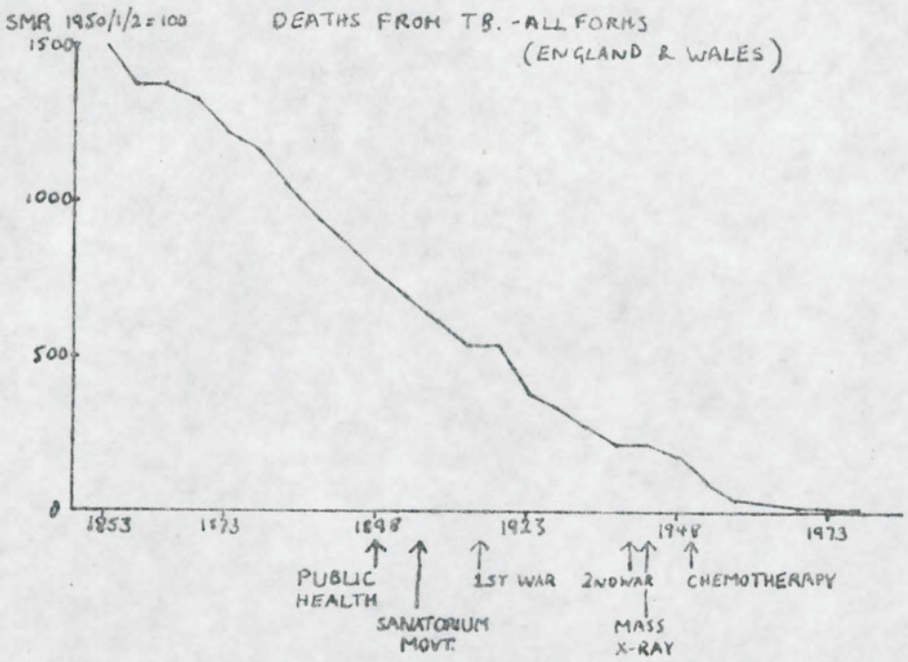


FIGURE 2

Death rates from tuberculosis from 1881 to 1981 related to pub health measures, the sanatorium movement, World Wars 1 & 2, mass X-ray a chemotherapy. The fall is uniform except for brief static periods durin the Wars.

At the moment, little can be done to detect occlusive vascular disease before symptoms occur. Attempts to educate the public in measures to prevent such disease are of necessity inadequate because so little hard information is available about the causative factors and natural history of the disease process, particularly in its early stages.

1.4 Historically, the conquest of most diseases has not been achieved by intervention with dramatic surgery and high technology medicine applied to the management of end state disease; rather by an understanding of the disease process itself, knowledge of its causative factors and public awareness of the need for preventive measures.

For example, tuberculosis was not relegated to near social irrelevance as a result of the sanatorium movement, nor by chest surgery, nor even by the introduction of anti-tuberculous drugs. The mortality from tuberculosis has fallen steadily for over a century. Fig.2 illustrates the steadily diminishing death rate and relates this to the ineffectual medical interventions; better housing, public awareness and two World Wars did have positive and negative effects.

The evidence for the decline in the incidence of tuberculosis is paralleled by many other diseases, notably the infectious diseases which were virtually conquered before the introduction of antibiotics.

Coronary artery disease and stroke, by contrast, continued to increase until recently. There is evidence that during the past few years in the United States, possibly because of public awareness and interest, the incidence of coronary disease has begun to fall. Similar trends are just beginning to show in England & Wales. Rheumatic heart disease is virtually eliminated from the more affluent countries by better social conditions. Why therefore are similar principles not applied to occlusive cardiovascular disease?* (see footnote).

The medical profession might have been expected to shift its interest away from the unsatisfactory management of end state disease to early detection and prevention. There is sound historical reason for the development of cardiology. In its present form,

* Occlusive vascular disease (completely or partially blocked arteries) is the underlying disease process causing coronary, stroke, peripheral vascular disease (pain in the calves when walking) and some senile dementia. The actual process is discussed in Appendix 2.

cardiology is the study of heart disease, not its prevention. Until a mere 35 years ago, medicine could do little for any form of cardiac disease other than to alleviate its symptoms with drugs. There was little incentive, apart from academic satisfaction, for accurate diagnosis. Vague terms such as apoplexy and anasarca were used to cover stroke, the acute coronary and a failing heart.

The combination of surgical ambition to open the last chambers in the body and the surfeit of plastics and electronics technology available after World War II made heart surgery possible. There was then an urgent requirement for the surgeon to know the exact nature and site of the lesion on which he was to operate. In the early days of cardiac surgery the time available for work within the heart was counted in minutes not hours; an incomplete or wrong diagnosis resulted in a dead patient. Cardiologists met the challenge. A second generation of cardiologists now exists capable of diagnosing anatomical lesions within the heart with remarkable accuracy.

1.5 The diagnostic techniques which are used require catheters to be passed into the heart, the use of X-rays and radio-active isotopes. All are potentially dangerous.

Nevertheless, used skilfully, invasive cardio-diagnosis is now capable of producing detailed anatomical studies of the heart and the blood vessels supplying it, occasionally with great discomfort, but, in skilled units, with insignificant mortality. The surgeon sometimes still has to operate on patients in whom the diagnosis is inadequate, for although the lesion may be anatomically defined, the heart muscle may be undetectably irreparably damaged and the patient unable to survive.

1.6 Cardiologists have been less desirous and less able to measure essential heart function than structure. The diagnostic techniques used are still mostly directed towards assessment of structural abnormality, not functional disturbances and towards producing images not performance figures. The remarkably successful efforts to produce images have obscured the need for vital functional data which is more difficult to understand. The function of the heart is to pump blood without unnecessary expenditure of energy.

2.1 The concept of assessing the efficiency of the heart as a pump (albeit an extremely complex one) upon which life in all organs, including the heart itself, depend, is central to the idea of the mobile diagnostic unit.

A pump can fail to work efficiently for a multiplicity of reasons:

a) It is not designed or built properly (failure in genetic design or construction: congenital deformities).

b) It is damaged (by disease processes, such as viral illnesses, rheumatic fever, alcoholic myocarditis and heart antibodies etc.).

c) The valves become blocked or leak (heart valve disease either rheumatic or due to wear on congenitally abnormal valves).

d) Because it is consistently called upon to perform a task which is beyond its design capability (pumping against a consistently elevated blood pressure, or at an excessive volume rate etc. due to abnormal control mechanisms, or external influences such as over-production of thyroid and other cardio-active hormones).

e) Its power supply is inadequate (the blood vessels supplying the heart and coronary arteries with energy may be partially blocked).

2.2 Diagnostic techniques originally intended for detailed anatomical diagnosis are not capable of detecting pump failure due to excessive demands, or an inadequate power supply, until the disease process is far advanced.

2.3 The fit heart has a capacity to pump blood in excess of the body's everyday requirements. Any inadequacy of its power supply will not be manifest until the heart has to meet considerably increased demands. Even in situations when increased output requirements cannot readily be met by the under-nourished heart, it may appear to be coping normally in the short-term without symptoms. Compensatory mechanisms exist both within the heart itself and in the body to overcome such short term pumping deficits. The heart can incur a temporary energy debt whilst the body can for short periods divert blood from non-essential areas.

Even over a long period, a heart working with a diminished blood supply may be symptom-free except in periods of exertion when breathlessness or pain may occur.

2.4 When symptoms of cardiac inadequacy do occur, heart disease is already well advanced. It is known that the area of one or more major vessels supplying the heart muscle with blood can be reduced by 70% without producing symptoms. Post-mortems on allegedly fit young U.S. servicemen killed in the Vietnam war revealed remarkable evidence of unsuspected occlusive coronary disease in the apparently very fit fighting soldier.

2.5 There is a powerful argument against leaving contemporary medical thought and diagnostic techniques to solve the problem of early detection. Occlusive vascular disease must be searched for in its early stages in the asymptomatic general population. Painful and potentially dangerous invasive techniques such as cardiac catheterisation and methods involving the use of X-ray and radio-active isotopes cannot be used. Even if it were argued successfully that invasive methods could be used in the early detection of the disease process, it would not be feasible to use them repeatedly, say every 9 months.

3.1 Two changes in medical thinking are required if the disease is to be detected at the earliest stages.

a) Instruments must be designed specifically for early detection, to measure function with sufficient sensitivity to detect disease and degeneration of performance before symptoms arise. They must, of course, be non-invasive, and not unpleasant to the patient.

b) Along with this change in diagnostic technology must go a desire to prevent the disease reaching the end state, i.e. that state whose management is the foundation on which our present health care system is built.

3.2 The arguments which might be used against screening for heart disease are similar to those against screening for any disease process. They do not, however, apply in this case.

Screening for relatively uncommon diseases may be so cost ineffective as to be worthless. The massive incidence of heart disease negates this argument. Most screening has been done for various forms of cancer, notable examples being soft tissue X-rays for breast cancer and the cervical smear for cancer of the neck of the womb. There is doubt as to whether

intervention in breast cancer makes any significant difference to the outcome and there is tenuous evidence that soft tissue X-rays might even increase the incidence of cancer in the breast. The actual procedure is uncomfortable, since the breast has to be clamped in a machine under considerable pressure. The cervical smear is not exactly a non-invasive procedure, and it has arguably not shown itself to be as valuable as hoped in reducing deaths from cancer of the cervix.

Detection of other cancers, such as those of the pancreas or stomach at an early stage might conceivably lengthen the life expectancy of the sufferers from a potential life span measured in months to one measured in years. The survival rate from a discovered cancer of the stomach is such that only a few percent are alive at the end of a year. The discovery of lethal, untreatable diseases by screening increases human suffering rather than reducing it.

The siutation is quite different with heart disease. The time taken to die after the initial coronary attack may be many years. There is evidence in the experimental animal that the disease process can actually be reversed, and evidence in man that removal of certain causative factors (risk factors like smoking and obesity) can restore a potentially diminished life expectancy to that of the general population. In the experimental laboratory, biological extracts to control the development of occlusive vascular disease and even to reverse its progress show considerable promise. Some extracts of naturally occurring compounds are presently undergoing clinical trials. For these reasons, the usual arguments against screening do not apply to the cardiovascular system.

3.3 Some cardiovascular disease is so universal (at least 50% of the adult population) that a false-positive test would not have such dire consequences on the subject and his family, as say, a false-positive for a breast cancer or a cancer of the cervix. It would merely result in a stricter and better lifestyle for the subject. In sections 1.5 and 1.6 the shortcomings of invasive cardiodiagnostic techniques, their dangers and the irrelevance of the data they produce were pointed out.

Non-invasive, painless, harmless tests which are not unpleasant to the patient can be carried out to assess cardiac function. The tests available before the advent of nuclear magnetic resonance have not all been widely used in cardiology for several reasons:

a) They did not yield the detailed anatomical information required by cardiologists assessing patients for surgical treatment.

b) They did not yield images which could be discussed and stored.

c) Most importantly, each non-invasive instrument used in isolation is relatively weak. Often they are troublesome to use. The incentives to purchase and use an instrument which requires great operator skill, and which yields only weak information about an aspect of an organ not central to the requirements of anatomical diagnosis, are small.

3.4 The proponents of various non-invasive instruments have sometimes claimed that they are capable of producing more information than is in fact the case. They have tried to make non-invasive instruments produce data which fits the thought processes of the traditional cardiologist and the cardiac surgeon. For example, the transcutaneous aortovelograph (TAV machine) was designed to measure the acceleration of blood ejected from the heart, an important measure. This it does quite well in the patient in whom there is no lung in the way of the ultrasound beam. Acceleration of blood, however, is information not readily understood or appreciated. Attempts to measure the cardiac output and other better known parameters using this instrument have not been successful. Another example is the impedance cardiograph which measures changes in electrical resistance between a conducting band round the neck and one round the abdomen, plotted against time. The curves produced are complex and probably informative, but again they do not tell us about cardiac output and cannot produce familiar images of the anatomy of the heart.

3.5 Nuclear magnetic resonance (N.M.R.) suffers few of the limitations of other instruments. Using computer based predictive cardiac gating, low field N.M.R. can produce finely detailed static images of the heart. These can be in the form of single slices, multiple slices or blocks of data. Using N.M.R. techniques at their limits, acceptable "movie" images can be produced. It is already known that coronary arteries can be visualised in their long axis and transversely. Blood flow measurements are already possible in larger vessels

and will probably soon be available in coronary arteries. Atheroma can similarly be seen in large vessels, hopefully soon to be measured in coronary arteries. At the moment all the low field measurements depend on proton density. Some advances, utilising basic physical principles, suggest that low field machines may be used to measure the concentration of metabolites other than water, notably potassium and phosphorus.

3.6 High field N.M.R. machine can be used to assess some biochemical processes directly. The levels of energy rich and energy poor phosphorus metabolites have already been measured using a technique known as topical magnetic resonance (T.M.R.). This technique produces only vague images but important clinical data.

These high field machines are not suitable for use in the M.D.U. for several reasons, notably:

a) The high fields require expensive liquid helium cooled superconductor magnets, or resistive magnets with large current consumption and corresponding cooling requirements.

b) High field magnets are readily disturbed by moving masses of metal such as passing cars.

c) High fields are hazardous to pacemaker patients at distances up to 30 feet. Similarly metal objects can be pulled into the magnet causing injury.

The use of low field N.M.R. machines in the M.D.U. will probably not prove to be disadvantageous in any way. The use of high field machines may soon be shown to be unneccesary and will, therefore, be abandoned.

Although N.M.R. used alone will provide most of the information required for cardiac diagnosis, its use in early detection will be enhanced by combining it with a limited number of other non-invasive instruments.

4.1 There follows a brief review of existing well tried, and new non-invasive instruments, from which the few chosen for the M.D.U. were selected, (see Table 1) listed here arbitrarily, in alphabetical order bearing no relationship to their importance (see page 12).

Apex cardiograph (ACG)

Ballistocardiograph (BCG)

Compliance cardiograph (CCG)

Displacement cardiograph (DCG)

Central Doppler methods (Doppler)

Other peripheral Doppler methods (Doppler)

Echocardiograph - various forms (Echo)

Electrocardiograph (ECG)

Frequency cardiograph (FCG)

Impedance cardiograph (ICG)

Magnetocardiograph (MCG)

Mass spectrometer (MS)

MAVIS 'C'

Nuclear & topical magnetic resonance (NMR & TMR)

Percutaneous blood gases (PCBG)

Superconductor quantum interference device (SQUID)

Systolic time intervals (STI)

Thermography (Therm)

Transaortic velography (TAV)

TABLE 1: Potential value of instrument/technique in clinical area

	ACG	BCG	CCG	DCG	DOPPLER	ECHO	ECG	FCG	ICG	MCG	MS	MAVIS 'C'	NMR & TMR	PCBG	SQUID	STI	THERM	TAV
Screening of normal population (MDU)	3	1	4	3		4	4	4	1	0	2	3	4	2	?	4	2	2
Preliminary O/P studies	2	1	2	2		4	4	4	1	0	2	2	4	1	?	3	1	1
Cardiac catheter back-up	1	1	0	2		3	4	3	1	0	2	1	4	1	?	1	1	1
Monitoring in theatre	0	0	0	1		1	3	1	1	0	2	1	0	2	?	1	1	0
Monitoring in ICU & CCU	1	0	0	1		2	3	1	1	0	2	2	0	2	?	1	1	1
O/P follow-up & prevention	3	1	1	3		3	3	3	1	0	2	2	4	2	?	3	1	1
Use as research tool by itself	1	1	3	2		3	3	3	1	0	2	2	4	2	?	3	0	1
Use as research tool in combination	3	2	4	3		4	4	4	3	1	4	4	4	4	?	4	2	2
See note no.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18

Scoring key:
4 - maximum utility
3 - high diagnostic potential
2 - definitely applicable
1 - of possible slight value
0 - inapplicable
? - not yet known

* Areas of importance for early diagnosis studies by MDU

TABLE 1A: Section of cardiac cycle studied

	ACG	BCG	CCG	DCG	DOPPLER	ECHO	ECG	FCG	ICG	MCG	MS	MAVIS 'C'	NMR & TMR	PCBG	SQUID	STI	THERM	TAV
Systole - before valve opening	1	0	0	2				3	0	0	0	0		0	?	4	0	0
Systole - between valve opening & peak pressure	2	1	0	1				0	2	0	0	3		0	?	3	0	4
Systole - between peak pressure & valve closing	3	1	0	1				0	2	0	0	3		0	?	1	0	2
						SEE NOTES							SEE NOTES					
Systole - between valve closing & lowest vent. pr.	4	1	0	2				0	0	0	0	3		0	?	0	0	1
Diastole	1	0	0	0				0	1	0	0	3		0	?	0	0	1
General circulatory status	0	0	4	0				0	0	0	3	4	2	3	?	0	3	1

Scoring key:
4 - maximum utility
3 - high diagnostic potential
2 - definitely applicable
1 - of possible slight value
0 - inapplicable
? - not yet known

* Areas of importance for early diagnosis studies by MDU

PRACTICAL NOTES ON TABLE 1

These notes relate only to selection of the instruments and are not intended to be exhaustive. See appropriate appendices for fuller discussion of the instruments themselves.

1. APEX CARDIOGRAPH (ACG)

The present mechanical system is cumbersome but gives good information concerning relaxation of the heart. The ACG is already used in combination with the echocardiograph. The information given is accepted by many cardiologists. Many potential improvements using Doppler sound and R.F. are under development.

2. BALLISTOCARDOGRAPH (BCG)

This instrument has its problems, related to satisfactory attachment of the patient to the instrument, and to problems in transducer design. Nonetheless, it gives a lot of information, some of general interest and some of interest to specialist cardiologists.

3. COMPLIANCE CARDIOGRAPH (CCG)

A method using two Doppler probes to determine the rate of propogation of the pulse wave in order to determine the flexibility of the vessel wall.

4. DISPLACEMENT CARDIOGRAPH (DCG)

This yields very good empirical results when used by a trained operator. Incorrect siting of the transducer over the patient can distort the signal. It has great potential but further research is required before it can be incorporated in the combined instrument system.

5. DOPPLER (SEE MAVIS 'C' & TAV)

Useful when measured by Doppler shift combined with echo cardiography in conjunction with non-invasive blood pressure measurements to gain information on the state of the peripheral blood circulation.

6. ECHOCARDIOGRAPH (ECHO)

This instrument can be used in several modes. It is non-invasive and has received the largest amount of investment during its development. Its ultimate value is limited by shadowing and the slow and variable speed of sound in body tissues. Resolution is limited by the physical properties of ultrasound producing sidelobes, blurring etc. It gives good imaging data and some mechanical information about the heart. It can be used with computer technology to examine movements of parts of the myocardium across the whole of the cardiac cycle. Computer

technology has also extended the value of the echocardiograph by allowing analysis of the reflected wave from within the muscle mass as a method of assessing scarring, infiltration of fibrous tissue and possibly the blood supply.

7. ELECTROCARDIOGRAPH (ECG)

This is the oldest of the non-invasive instruments, about which a mass of empirical information is available. Its output is well trusted but without exercise this can be unhelpful. The Avionics treadmill is well set up to maximise information from the exercise ECG. Spatial and high frequency ECGs require further study. The ECG is essential as a reference for timing other instruments in the combined system. Although the ECG does not give direct information about the mechanical performance of the heart, multi-lead spatial ECG does give information about areas of the heart which can be expected to be non-contractile.

8. FREQUENCY CARDIOGRAPH (FCG)

This is a new system being developed at the National Heart Hospital, London. It promises to be a method of obtaining pressures inside the heart by non-invasive means. It depends heavily on a major computer program. It has already had a successful pilot study.

9. IMPEDANCE CARDIOGRAPH (ICG)

This produces empirical information from which several parameters, such as cardiac output, can be theoretically derived. A mass of empirical data exists about "point in time" comparisons with invasive studies. It needs further continuous assessment.

10. MAGNETOCARDIOGRAPH (MCG)

This measures expensively and with difficulty the very weak magnetic field associated with the electrical activity of the heart. The ECG is probably more informative.

11. MASS SPECTROMETER (MS)

This does not give direct information about any part of the cycle but can be used to give a measure, non-invasively, of the cardiac output. It can also be used to measure percutaneous blood gases, which can also be measured using fuel cells. The transpired skin gases are unreliable in a collapsed patient.

12. MAVIC 'C'

This Doppler ultrasound instrument gives accurate measurement of peripheral blood vessel size, blood flow, the velocity profile, and the presence of turbulence. It is vital for an assessment of the general state of the circulation and blood flow to the brain.

13. NUCLEAR & TOPICAL MAGNETIC RESONANCE (NMR & TMR)

This technique is still under development. Cine-films of the beating heart have already been produced. The problems of improving picture quality are solved. Oxygen affects magnetic images and this effect has allowed the use of oxygen as a marker. Other N.M.R. markers are under investigation. Peripheral blood flow measurements and measurements of phosphates in muscle have also been made. Problems arise from the lack of portability and from the effects of magnetism on other objects, e.g. pacemakers.

14. PERCUTANEOUS BLOOD GASES (PCBG)

An excellent device for obtaining pO_2 (concentration of oxygen in arterial blood) and pCO_2 (concentration of carbon dioxide in arterial blood) when used in combination with thermography to define areas with blood flow.

15. SUPERCONDUCTOR QUANTUM INTERFERENCE DEVICE (SQUID)

This is a new instrument which may be useful in determining biochemical changes in heart muscle and other tissues. Its role is as yet undermined. Its suitability for the M.D.U. is under investigation.

16. SYSTOLIC TIME INTERVALS (STI)

A well-known method of assessing cardiac performance.

17. THERMOGRAPHY (THERM)

The technique of comparing peripheral temperatures with core temperatures is commonly used to determine whether the peripheral circulation is deteriorating or improving. A thermoscan can be used to give more accurate information about the changing peripheral circulation.

18. TRANSAORTIC VELOGRAPHY (TAV)

In suitable subjects and when used by skilled operators, this gives valuable information about the acceleration of blood from the heart, total blood flow, cardiac output and sometimes of coronary flow. It is not suitable for all patients.

Used singly, each of these instruments can contribute little to our knowledge of cardiac function. If a patient were sent from department to department to be assessed non-invasively on a range of instruments, the clinician trying to study the patient would have before him a series of unrelated traces run on different sets of heartbeats with no time relationship between them.

Only a few centres in the world have working N.M.R. machines and no centres exist where all the non-invasive instruments are available and used simultaneously on any patient. Hospitals and clinics do exist where several non-invasive instruments may be used independently and randomly and the physician may attempt to correlate the data they produce.

4.2 With modern computer techniques for data acquisition and processing, a new potential exists for using a series of non-invasive instruments simultaneously on a run of 180 heartbeats, also used to construct an N.M.R. block of data. This one step enhances the diagnostic power of these instruments in several ways. At the simplest level they are time related and looking at the same heartbeats, but the advantages of their combination are far greater than accrue from this single benefit. In section 2.1 the heart was considered as a complex pump. The main pumping chambers of the heart have a filling phase and a pumping phase. The first part of the pumping phase serves to raise the pressure within the chamber sufficiently to open the outlet valve. The second part of the pumping phase actually does useful work in moving blood into the circulation of the lungs or of the body. After ejection is complete the pumping chambers spring open to recommence filling. In Table 1 which lists the value of the various non-invasive instruments currently available and being developed, it can be seen that some instruments are better at looking at one part of the cardiac cycle than another. In 1921 a physiologist Carl J. Wiggers plotted the time relationships of the pressure changes in the various chambers of the heart. Figure 3a shows schematically some events in the cardiac cycle relevant to this discussion. Figures 3b and 3c show which parts of the cardiac cycle are best examined by various instruments.

4.3 Another novel part of the mobile diagnostic unit concept is that of combining a small number of key non-invasive instruments giving them mathematical weighting related to the part of the cardiac cycle which they examine best. The frequency cardiograph for example is mathematically zero rated except for the short period during ventricular pumping before the outlet valves open. The TAV machine is given zero rating during that phase of the cardiac cycle, but portrays best the next part of the cycle as shown in Figure 3a.

Another original part of this plan relates to further mathematical weightings adjusting the value of the information obtained from the various instruments in two more ways:

a) Relating to the accuracy and quality of the signal obtainable from the instrument under optimal conditions in the M.D.U. expressed as a fraction of the N.M.R. data (see Table 1 and notes).

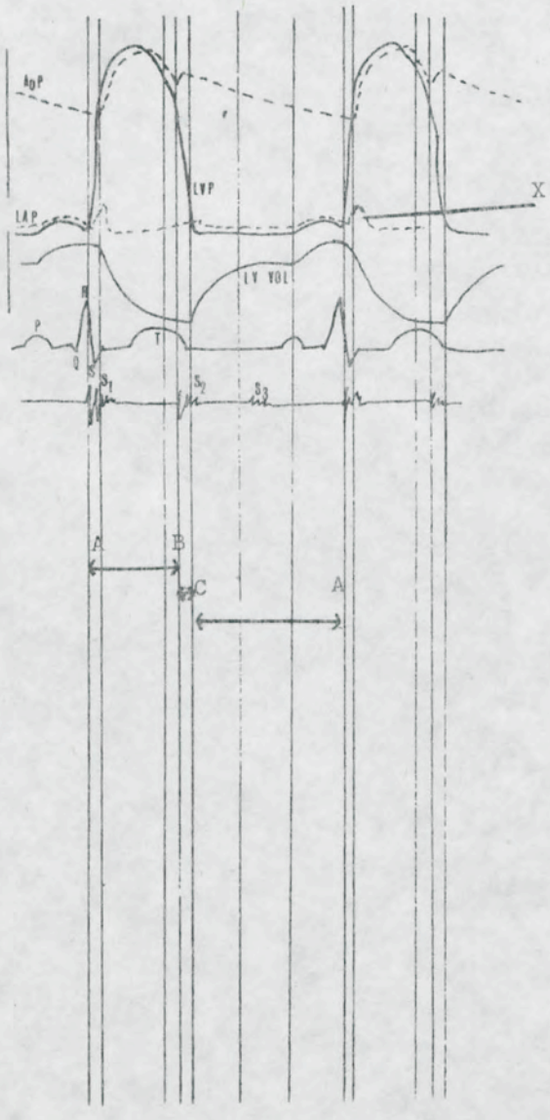
b) To the quality of the actual signal being analysed, rejecting data which contains noise.

It is anticipated that in a number of instruments examining a sequence of say 300 heartbeats, it should be possible to obtain and bank information from 180 heartbeats in which acceptable signals are obtained from all the instruments in use. It is necessary to examine excess heartbeats because the heart functions within a control framework depending on various feedback mechanisms. It will over-pump for a period and then under-pump, adjusting its output to the body's needs. Effects of breathing, emotion and the beginning and ending of even small amounts of exercise induce considerable changes in its performance. Trend recordings always show this "hunting" of cardiac performance. Detailed analysis of the performance of the heart is best done at the points of minimum change rather than those of maximum change. In an ensemble of 100 beats such points of minimum change will occur several times.

FIG. 3a

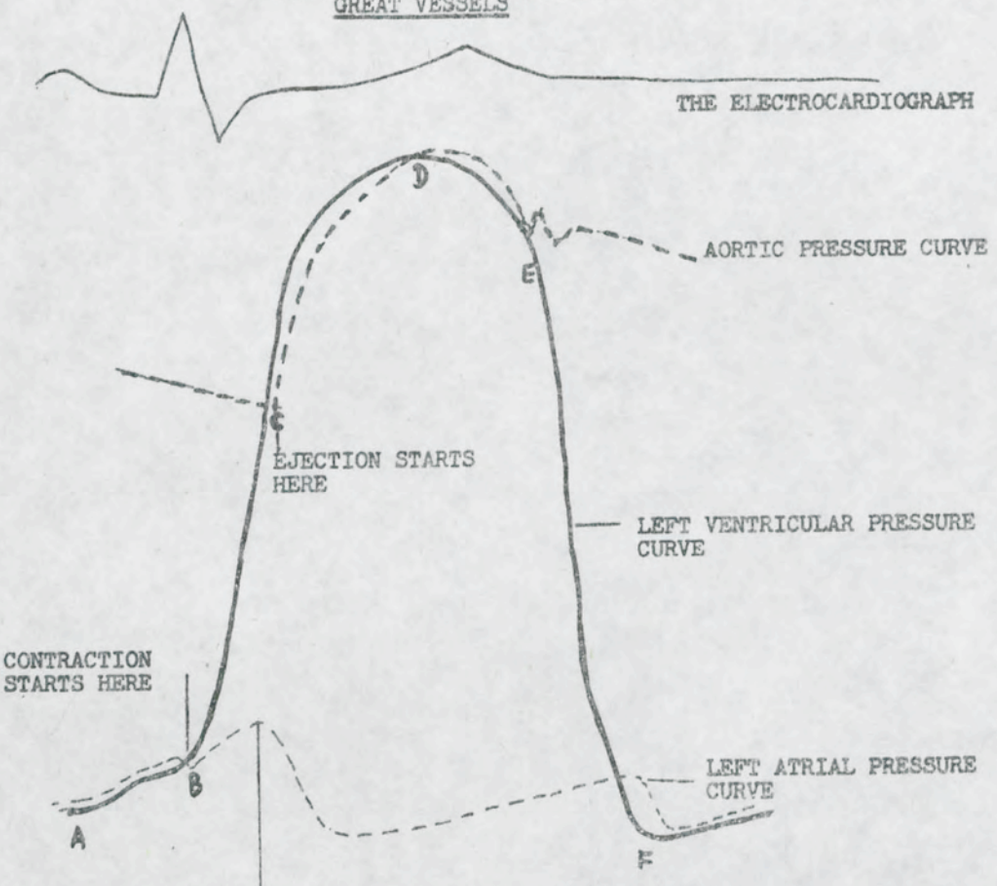
In this diagram the aortic pressure, the left ventricular pressure, the left atrial pressure, the left ventricular volume, the E.C.G. and the heart sound are all related to each other. Between line A and B the heart muscle is actively working and consuming energy. Between B and C, the active early diagnostic phase, a small amount of energy is being consumed and between C and A, during the remainder of diastole the heart is receiving the flow of blood from the coronary arteries. Therefore the slower the heart rate and the longer the gap between the working periods the better the ratio of blood supply to muscle work. Conversely a rapid heart rate means a less well nourished heart. Thus pulse rate is an informative natural non-invasive instrument. This can be detected by the Doppler shift instrument which can give further information as in the peripheral cardiograph.

X is the peak of the left atrial pressure curve related to the bulging back of the atrio-ventricular valve.



PRESSURE VOLUME CURVES IN THE HEART AND GREAT VESSELS

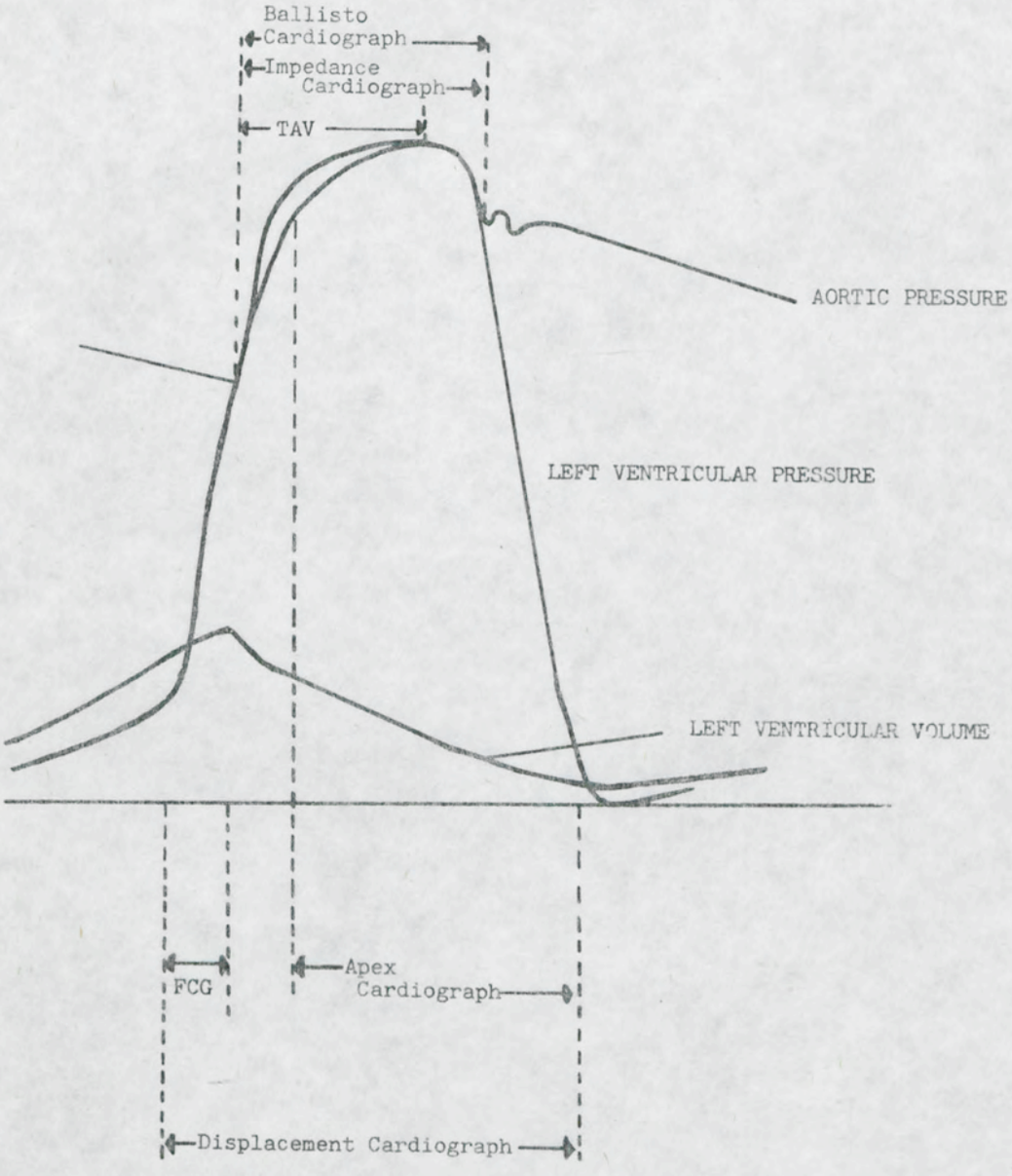
FIG. 3b



The pressure rise in the left atrium corresponding to the rise in left ventricular pressure before ejection starts demonstrates the bulging back of the mitral valve showing that the left ventricular muscle shortens during the isometric contraction phase.

The left ventricular pressure rises from Point A because it is topped up by atrial contraction. From Point B the rise in pressure is due to the onset of ventricular contraction. At Point C the aortic valve opens. By Point D the left ventricular pressure is beginning to fall off but inertia is still carrying blood forwards in the aorta. At Point E the aortic valve is closing and aortic pressure after an initial bounce begins to fall as blood flows to the periphery of the body and coronary flow starts. At Point F the ventricle has finished its mechanical work and opened itself into its cylindrical shape ready to accommodate blood which begins to refill the ventricles and causes the left ventricular volume to increase again.

FIG. 3c



THE RELATIONSHIP OF SOME OF THE NON-INVASIVE INSTRUMENTS TO EACH OTHER AND TO THE CARDIAC CYCLE.

5.1 The potential value of the mobile diagnostic unit lies in several areas:

a) Early detection of occlusive vascular disease, avoiding the need for expensive cardiac surgery and hospitalisation.

b) Clinical diagnosis of undetected established heart disease.

c) The monitoring of the efficacy of preventive therapies, drugs and diets etc. without the need to wait for a generation.

d) As a research base for the evaluation of new non-invasive instruments by comparing them with data from well tried and validated combined instruments.

e) Chance finding of other treatable diseases.

f) Fitness tests for aircrew and other key personel which virtually eliminate risk of acute cardiovascular dysfunction.

5.1a Early detection of occlusive vascular disease

Combination and enhancement of the diagnostic power of non-invasive instruments improves their resolution of disease processes. When an instrument without enhancement would only respond when the cross sectional area of the coronary arteries were reduced so extensively that cardiac performance is impaired, an enhanced set of instruments should be able to respond when only a small reduction of cross sectional area is lost. N.M.R. is capable of looking at the vessel wall directly measuring atheroma deposition and would anticipate even this event. The mobile diagnostic unit will detect a whole range of pathologies in patients who would be assessed as normal by present day techniques. Even in a cardiac centre, these newly discovered pathologies will consist of presently undetected early disease not recognised or described. Since the unit is designed to measure overall heart performance, (ultimately expressed as a single figure - the cardiac performance index) repeated examination of patients allows not only for the detection of early pathology but also its severity to be quantified. The scale of such measurement would be a continuous spectrum ranging from "very healthy" to the borders of symptomatic disease (Fig. 4).

5.1b Clinical diagnosis of undetected established heart disease

A patient presenting himself for screening may have attributed mild symptoms of serious heart disease to "indigestion" or some other vague self diagnosis. He may have deemed it was unnecessary or impractical to see his doctor. Even in a health centre, a G.P. does not have the facilities or the time to perform an adequate cardiac assessment of the patient. The computer enhanced diagnostic power discussed in previous pages allows diagnostic facilities well in excess of those available at some of the best hospital out-patient departments or private screening clinics. For these reasons, the mobile diagnostic unit would allow exhaustive evaluation of relatively advanced symptomatic disease, although this is not its primary function.

5.1c Monitoring of the efficacy of preventive therapies etc.

The ability to measure the presence and to quantify the severity of early disease, means that by repeated measurements improvements or losses in performance could be established. A subject in the study whose performance was deteriorating more rapidly than mere ageing could account for, would be one in whom therapy and the institution of all known preventive measures should be applied. If the therapy were successful, subsequent cardiac performance indices would show arrest or even reversal of this accelerated decline. If not, the decline would proceed unchecked. In this way, the usefulness of certain manoeuvres in treating or preventing occlusive vascular disease would be ascertained in less than a tenth of the time that it currently takes. The results would also be more accurate and more complete than those currently obtained by waiting a generation to study mortality figures.

5.1d As a research base for the evaluation of new non-invasive instruments

Once the mobile diagnostic unit is running it will provide an ideal baseline for comparison for newly invented non-invasive instruments. At present these are capable of producing trend records over a long period of time and evaluated by comparing a point in time with invasive catheter laboratory data which itself is distorted because of the laboratory environment.

5.1f Fitness tests

At present air crew and key personel frequently are passed as fit by an ECG, while others are denied a livelihood on the basis of an abnormal ECG which may be insignificant. The diagnostic power of an M.D.U., including nuclear magnetic resonance, is so great that it should be possible to guarantee that there will be no cardiovascular catastrophe possible within the next month or two, with rare exceptions of rythmn disturbance, ruptured congenital aneurysms etc.

6.1 The mobile diagnostic unit is aimed at detecting occlusive vascular disease, including coronary artery disease, at its earliest stages. It must be designed to measure the earliest occurrence in the chain of events which leads to symptomatic coronary artery disease.

6.2 Three approaches are available (not mutually exclusive):

a) To look directly at the coronary artery walls to detect some aspect of them which becomes abnormal at an early stage (N.M.R.).

b) An alternative is to detect the results of abnormality of the coronary arteries by measuring changes of flow in the coronaries directly, non-invasively using N.M.R.

c) By measuring changes in the pumping performance of the heart and the synchrony of its contraction. Although the abnormalities in pumping action are not the earliest events in the chain (since they are caused by partially blocked coronary arteries) they are closer to these events than the onset of symptoms

MOBILE DIAGNOSTIC UNIT COSTINGS

CAPITAL COSTS ALL AT JANUARY 1983 PRICES (Approx to 0.5K/item)

Instrumentation costs are approximate. Research at the National Heart Hospital is underway to define which instruments are essential and which may be discarded. The new generation N.M.R. equipment is central to the project.

Instrumentation

a) DIAGNOSTIC - including new generation constrained field N.M.R.

Electrocardiograph for timing	
2D echocardiograph	
Compliance cardiograph	
Apex cardiograph	
Frequency cardiograph (computer programme plus simple phonocardiogram)	
Arterial pulse recorders for CCG	
MAVIS or equivalent	300K

b) GENERAL

Video recorder) For patient who is waiting,	
Colour TV) giving information about	
Cost of video film) examination	
Computer interrogation terminal using simplified keyboard	
Software for computer interrogation (included in main software package)	25K

c) COMPUTER EQUIPMENT

Main Trivector computer system to control instruments/process data	
Software for same	150K
Colour TV monitor for computer system output including CTV converter	
Hard copy printer for computer system output	150K

d) PATIENT DATA SOTRAGE (Mobile Unit)

Magnetic card record system for patients	
Terminal to read/write magnetic cards	
Back-up hard disc system for data storage & computer "note taking"	
Radio (telephone) link for clarification of records and to call in emergency maintenance, ambulance, etc. (hopefully to use Air Call system) + running costs	15K

Power supply

G & M ONAN vibration-free generator	5K

Crew accommodation

Staff sleeping accommodation	
Cooking facilities	
Refrigerator	
Staff washing facilities	
Water supply	inc. in gen. fittings + 1K

Emergencies

a) VEHICLE BREAKDOWN/INSTRUMENTS BREAKDOWN

Fire extinguisher - FREON autofire	
Tools for vehicle repair	
Tools for adjustment of instrumentation	

b) PATIENT COLLAPSE

Resuscitation trolley with defibrillator	
ECG monitor	
Drip stand	
Drug cupboard	10K

Internal fitting of vehicle as (mobile) clinic

Lining walls	
Cupboards	
Benching	
Wiring	
Lighting	
Soft furnishings e.g. chairs in waiting area and for computer interrogation, also couches.	
Air conditioning/heating	15K

External fitting of vehicle

2 educational films to run simultaneously (including cost of films)	
2 television sets for showing films	
2 videorecorders for showing films	
Awning to keep spectators dry and cool	
Umbilicus for connecting to a hospital switchboard	
Sockets, wires & system for transmission of day's data to central computer via telephone system (unless radio-link above can be used)	20K

Central hospital computing office (research)

Trivector main computer	
VDU with keyboard	
Hard copy printer for generating letters	
System for communicating by telephone with mobile units	
Radio telephone link (? on Air Call system)	
Disc/tape system for main aspects of data storage	
Software to service above	12K

Vehicle

1½ decker low cab bus with WC's	60K

RUNNING COSTS FOR FIRST YEAR - including training costs for staff for subsequent M.D.U.'s and research overheads

Staff

a) MOBILE UNIT

1st doctor (including 20% overhead National Insurance etc.)	12K
2nd doctor	10K
State Registered Nurse	9K
Technician	9K
Driver (casual labour)	0.5K

b) CENTRAL HOSPITAL COMPUTER SYSTEM (RESEARCH)

Clerks to operate system/radio link	7K

Consumables

a) FOR COMPUTER SYSTEM (MOBILE)

Hard discs Paper for printer	3.5K

b) FOR CENTRAL COMPUTER SYSTEM

Hard discs, floppy discs & magnetic cards Back-up tape Paper for letters produced by printer	1.5K

c) FOR TRANSDUCERS

e.g. ultrasound jelly ECG electrode jelly & other incidentals	1.5K

Fuel

Diesel for bus Diesel for vibration-free generator	0.5K

Radio telephone/telephone links

Standing charges Running costs	0.5K

Mail

Costs of postage to patients & GPs	0.5K

Insurance

Insurance/road tax of vehicle Insurance of instrumentation/mobile computer Insurance of central computer facilities	1K

Maintenance

Maintenance of vehicle Maintenance of instrumentation/mobile computer	1K
Contract with Trivector Maintenance of central computer facilities Contract with Oxford Instruments (or other)	10K

Entertainment

Literature for publicity Catering for local dignitaries & GPs/ health centres Circularisation/publicity costs	up to 10K

N.B. 2nd and subsequent years, including possible use of D'Arcy, Macmannus & Maceus, and Welbeck for public relations 5K

ORGANISATION OF THE M.D.U. PROJECT

Co-ordinator & Chairman of Meetings

Mr. J. R. Stephenson, C.Eng., M.I.E.R.E.

Originator & Director of Project

Mr. D. B. Longmore, F.R.C.S.Ed.

Advisors to Project

Mr. A. S. Ball (Computers)

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Mr. D. B. Forbes (Fund Raising)

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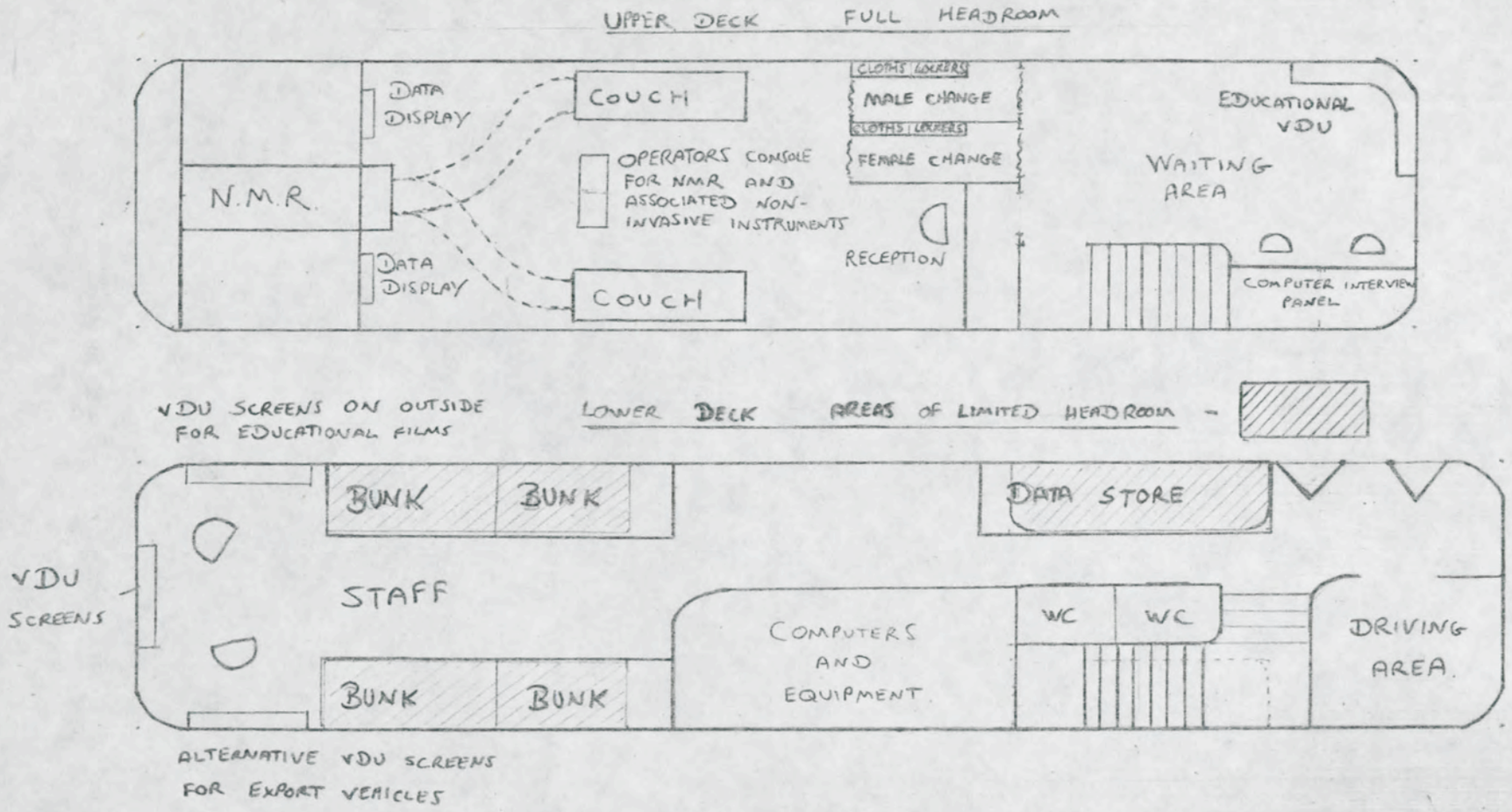
Secretary

Miss L. J. Pehl, A.M.S.

FIG. 5 Suggested diagrammatic layouts for trailer unit



A suggested layout for the vehicle is shown diagrammatically in Fig. 5.

The likeliest of the existing non-invasive instruments to be used in association with N.M.R. ar listed in the section on costs. The first unit is designed as a prototype for field study. The experience gained with the first unit will be used to refine the design for future units.

A P P E N D I X 1

FORMAT OF LETTER TO G.P. FOR MODE 1 OPERATION OF UNIT

Dear Doctor,

The M.D.U. is a registered charity. It has a mobile diagnostic unit which, using safe, painless non-invasive instrument in a new way appears to be capable of diagnosing early vascular occlusive disease before it progresses to coronary and stroke. The unit is staffed by two senior doctors and a nurse. It will be available to demonstrate to you its capabilities in the week starting .....

We suggest that it might be of interest for you to be screened yourself and for you to bring your family along for a check up. In addition to showing you the unit we would show you a two-tier educational video demonstration which explains the procedure, its significance and what preventive measures might be taken.

The first video film is intended for the interest of you and your colleagues, the second is for whichever of your normal list of patients you may wish to refer for screening.

The unit will be capable of evaluating 100 to 300 of your practice at each visit. We would of course like to follow their progress at intervals of not more than one year. This will enable us to study the natural history of heart and general vascular disease as a research project. In addition, we could help you to monitor the efficacy of any preventive measures you recommend to your patients. We look forward to hearing from you and to co-operating with you in this venture.

For some categories of subject a small charge will be made. A proportion of this will be paid to pay for the extra work involved.

For this study it is hoped that you will be able to select subjects who are well-established in your area and likely to be available for further evaluation at six to nine monthly periods. It is hoped that we can work closely together helping you with a follow-up capability using the computer in the mobile diagnostic centre to monitor your preventive measures, thus increasing the power of your clinical capability.

Yours faithfully,

CORDA
DETECTION PROTECTION PREVENTION

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The Coronary Artery Disease Research Association (Formerly HEART)
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it is possible that the myocardium thus preserved may be of little functional value (and, indeed, if it remains ischaemic it may even be arrhythmogenic), the limitation of infarct size by early beta-blockade obviously raises the possibility that such intravenous treatment may have an important effect on mortality.

But there is as yet no reliable, direct evidence. Fourteen small randomised trials[27-40] (on a total of only 2000 patients) have involved short-term treatment starting with only an oral beta-blocker but, as noted above, because of the slowness of an oral beta-blocker to take effect, their pooled relative risk (1·07, with standard error 0·14) is not only statistically but also medically uninformative. The seven randomised trials[23-25, 41-44] of short-term treatment that have at least started with an intravenous dose are unfortunately even smaller. So, even if the 1-week mortality in these trials is pooled with that in the three randomised trials[11,13,14] in which intravenous treatment was followed by long-term treatment, this yields a total of only 81/1569 control deaths and 76/1596 treated deaths. This difference is not statistically significant, but the figures do at least suggest that early intravenous beta-blockers need not be as hazardous as was once feared (especially if injected slowly, with close monitoring, into patients without contraindications such as severe failure, second-degree heart block, or unusual risk of bronchospasm).

Unfortunately, the uncertainty as to whether the promise of early intravenous treatment will be fulfilled has not been dispelled even by the excellent study of intravenous metoprolol followed by 13 weeks of oral metoprolol.[11] For, not only was the mean time from onset of pain to intravenous treatment so long (11·3 hours) that the overall mean enzyme reduction was hardly significant, but also the reduction in mortality was chiefly seen not in the first week (23 placebo versus 18 metoprolol deaths) but in weeks 2–13 (39 placebo versus 22 metoprolol deaths). Although mortality in weeks 2–13 might have been favourably affected by early treatment, it is impossible from that study to know whether it really was, or whether only the long-term treatment was important. Moreover, the preliminary results[14] from a similar, though smaller, study of metoprolol are somewhat less promising.

Thus, for the moment it is difficult to disagree with the consensus that emerged from a meeting in New York at which the results from the largest[1] of the long-term beta-blocker trials were presented and discussed. By randomisation in eleven trials of over 13 000 patients, the effects on mortality of long-term beta-blockade after myocardial infarction have now been reliably estimated; but, at present, those of early intravenous short-term beta-blockade during the actual development of myocardial infarction have not. And perhaps they will not be until many thousands of early treatments have also been randomly allocated.

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Brain Damage after Open-heart Surgery

THE mortality-rate for open-heart surgery—2·7% in 15 399 cases of congenital and acquired heart disease managed in six centres[1-6]—is only twice that reported for general surgery in a British teaching unit.[7] In the U.S.A., coronary-vein grafting is now as commonplace as hysterectomy and appendicectomy: some 100 000 are done a year, with a mortality rate of under 1%. Unfortunately, brain damage sometimes arises during these operations. The reported incidence has fallen—from 44% in 1970[8] to 15% in 1975[9]—but much depends on the sensitivity of the tests. Cerebral damage may not be obvious at routine follow-up, showing itself

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only to spouses and families in changes of mood or personality. After open-heart surgery, children underachieve.[10] In one American study, less than half the patients who were physically fit after coronary-vein grafting were at work[11] (in others[12,13] the proportion who returned to work was more encouraging). On the initiative of RODEWALD, SPEIDEL, and KATZ,[14,15] an international group of surgeons, anaesthetists, physicians, physiologists, psychologists, and other interested parties has been trying to devise tests which will detect damage without distressing the patient. In Britain, a Department of Health advisory group envisages a computerised central register which will quickly identify any types of equipment associated with brain damage. Meanwhile, what tests are on offer?

Firstly, there is the cerebral function monitor: both in animals and in man, abnormalities in the record correlate with events likely to cause brain damage during operation.[16,17] Next there are psychometric tests, including word rotation,[18] memory recall,[19] and conceptual logic;[20,21] the more exhaustive the tests, the more dysfunction emerges. These inquisitions, however, are not popular with patients or hospital staff just before an operation.[22] EYSENCK[23] has suggested that intelligence may correlate well with "average evoked potential",[24] so this is a possible non-invasive approach; another is nuclear magnetic resonance, for detecting areas of brain dysfunction. Then there is the information to be gained from cerebrospinal fluid (CSF). The level of creatine kinase BB isoenzyme in CSF correlates with brain damage[25] and has already been used to evaluate other techniques.[25] On p. 1139 this week, Dr ÅBERG and co-workers explore the potential of another enzyme, adenylate kinase, and the levels in CSF correlated with changes in intellectual function from before to after open-heart surgery. Nobody, of course, will think of doing lumbar punctures routinely in these circumstances but—if enough volunteers are forthcoming—CSF adenylate kinase could well prove a valuable index of the brain damage associated with different techniques of cardiopulmonary bypass. Another promising technique is regional cerebral blood-flow measurement by dynamic emission computed tomography after inhalation of xenon-133.[27]

Although the origins of the brain damage often remain a mystery, almost every aspect of the bypass procedure is unsatisfactory. The disposable apparatus through which blood passes is made of various plastics. Polyvinyl chloride is commonly used for tubing. PVC contains potentially toxic plasticisers and fillers, and its surface is rougher than that of endothelium.[28] Ethylene oxide, often diluted with freons, is frequently used to sterilise oxygenators and reservoirs. These gases loosely combine with the plastics and may not be fully desorbed before tubing is used; a long shelf-life certainly does not guarantee elimination of toxic residues.[29] During bypass, emboli enter the brain from various sources—debris from the circuit and the prime, flakes of plastic from the pump tube, silicone antifoam, and precipitates from added drugs[30]—but most are gaseous or from blood.

Heparin is used routinely as an anticoagulant with protamine reversal. Heparin interrupts the clotting cascade at various levels but stimulates platelet aggregation.[31-33] Continuous adequate heparinisation is not always achieved, so that thrombosis takes place.[34,35] Platelets are consumed and activated during bypass;[36,37] a 60% fall in platelet count is usual, and most of the remaining platelets are non-functional.[22] Prostacyclin (PGI_2), the most potent platelet

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stabilising substance yet discovered,[38-40] preserves platelet number and function, preventing platelet aggregation and deposition, and sparing heparin.[22,41,42] Routine use of prostacyclin should lessen the incidence of complications due to intracerebral thromboses, platelet emboli, and toxic materials arising from platelet granular release, and lessen the propagation of platelet aggregates on the surface of emboli from other sources.

Bubble oxygenation exposes blood to several square kilometres of gas without any protective layer, and to similar areas of antifoam; the result is haemolysis and protein denaturation.[43] Inadequate debubbling allows a constant stream of small gaseous emboli to pass along the arterial line, with greatly increased numbers during cardiotomy suction.[44] These bubbles can be detected in the carotid arteries. Many are very small and consist of pure oxygen; thus they may implode harmlessly. Other sources of gaseous emboli are cavitation bubbles with high energy levels, from maladjusted or damaged arterial pumps.[45] If the perfusionist allows the level to drop in the open-topped circuit, lethal air embolism can result. Filters trap air but present a large surface area for platelet aggregation. The volume of "surgical air" trapped in cannulae and the heart often exceeds that introduced from the pump.[44]

In the mistaken belief that a reduction of the blood gas flow ratio to around unity would lessen the chance of gas embolism, manufacturers have abandoned proven oxygenator designs. Physiological $PaCO_2$ and PaO_2 levels, on which cerebral blood flow depends, are now often unobtainable. The resultant low PCO_2 can make cerebral vessels constrict, so diverting blood to damaged areas where the blood vessels are unresponsive.

Finally, until better anticoagulants and equipment are available, there is a case for using drugs (with or without hypothermia) to protect the brain during cardiopulmonary bypass—in much the same way as cardioplegic solutions protect the myocardium.[46-49] Barbiturates,[49] etomidate (a non-barbiturate hypnotic anticonvulsant),[50] and flunarizine (a calcium blocker)[51] are possible candidates for this purpose.

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WHEN IS PULMONARY TUBERCULOSIS CURED?

SOME heated correspondence was provoked last year by Buechner in New Orleans,[1,2] who claimed that almost all previous trials of antituberculosis chemotherapy were either invalidated or wrongly interpreted. He blamed design faults and loose definition of words such as relapse and cure. Using strictly microbiological criteria, Buechner further concluded from his reinterpretation of existing studies that only a full 18 months of modern chemotherapy was sufficient to produce what he regarded as cure. His definition of cure ran thus: the patient's sputum should be rendered negative by both smear and culture at least six months before completion of therapy and remain negative for life. Such a strict definition does indeed invalidate nearly all existing work, but it contains serious flaws. First is the failure to recognise that a successfully treated (cured) patient may become reinfected; immunity is not absolute, and many previously treated patients are at increased risk of reinfection because of alcoholism, social deprivation, and other factors. A second flaw is the insistence on negative sputum for 6 months before discontinuation of treatment; in several studies—for example, the British Thoracic Association trial in the U.K.[3] and the Medical Research Council trials in Singapore[4] and Hong Kong[5]—patients have proceeded to a satisfactory clinical outcome with consistently negative microbiology despite positive sputum within the final six months of their chemotherapy. Lastly, it is absurd to insist that patients must be followed for life before a conclusion is drawn; if this were the case we should still be waiting for the results of the first streptomycin trial in 1948.[6]

Clearly Buechner overstated his case, but the ensuing correspondence served to highlight the difficulty in defining cure of tuberculosis—a difficulty exacerbated by the conflicting views of clinicians and microbiologists. Evidence from many trials suggests that the appearance after the completion of chemotherapy of one or two isolated positive sputum smears or cultures, preceded and followed by negative sputa, does not necessarily herald clinical relapse. From a purely microbiological viewpoint, such isolated positive cultures certainly make it difficult to pronounce the patient cured, even though he may be clinically well; conversely, they do not constitute a relapse, since the patient may have no further positive tests during many years of

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UNSAFE REGULATION

Government regulation rarely arrives slowly after studied contemplation. Rather, regulatory legislation usually springs from public reaction to an event which theoretically might have been avoided by regulation. Trade laws followed the public's first bitter taste of fraud. Motoring laws arose after the first fatal traffic accidents. In this regard, regulation of the pharmaceutical industry, which has developed apace over the past two decades, is not unique. Contemporary drug regulations arose out of the tragedies of a few early cases of apparently unsafe drugs provided to the public in the late 1950's and early 1960's. Regulations aimed at exceptions, in practice, have affected all drugs. The increasing encroachment of regulations has now reached the point of introducing new hazards, no less hazardous than the unsafe drugs they are directed towards.

The legislative growth which initially arose in the United States has spread. Politicians in Europe are obviously aware of American regulatory developments and may find it difficult to argue against similar legislation. Rigid United States standards are spreading as well, and are now being multiplied by varying standards in Europe.

The cry for safety without necessarily a reference to efficacy in our drug supply is politically popular, and therefore an easy standpoint for the politician. However, effective new drugs, albeit with their unavoidable effects, can save lives and vast sums; for example, chemotherapy for tuberculosis rapidly saved the cost of sanatoria and returned

people to a productive life. With each "scare" the regulatory bureaucracy tightens its grasp with no detectable consideration of the long-range threat to the public's well-being posed by the regulations themselves. Momentary concern over a particular drug inevitably leads to a more restrictive climate for all medicines.

The heightened regulatory pressure which followed the Medicines Act of 1968[1] in this country, and the 1962 Amendments[2] to the Food, Drug and Cosmetic Act of 1938[3] in the United States, has dramatically increased the amount of time and money required to bring a drug from the development stage to market. This is largely the result of a change in regulatory climate, rather than as a direct by-product of the legislation. Caution and delay have their natural effect upon new medicines.

The average pre-market time in both countries is approaching a decade, compared with approximately two years in the late 1950's and early 1960's [4]. During the same period, the average research and development cost per drug has increased from a few hundred thousand pounds in the United Kingdom and roughly half a million dollars in the United States, to a present range of £16-40,000,000[5] and $50-70,000,000[6] respectively. It is therefore not surprising to discover that the number of distinctly new medicines (as opposed to the so-called "me-to" drugs which follow a commercially successful drug) has decreased[7]. Such a decrease is a sobering demonstration of the loss of benefit from the advantages of modern science. There are

further dangers including developing "black market" practices (e.g. Laeotrile) and of commercial exploitation by countries which do not have the same safety standards.

Government regulation is by no means the sole cause of this alarming increase in the cost of drugs. In response to increasing litigation and fuelled by concern for public goodwill, the pharmaceutical industry has substantially increased its testing of new drugs. If the drug firms learned nothing else from the thalidomide episode in the United Kingdom and the MER/29 debacle in the United States, they at least received the clear message from the courts and public reaction that the marketing of an apparently unsafe drug will certainly not be to the financial benefit of the company. It is necessary only to consider the sum of over twenty million pounds (8) and the undisclosed millions of dollars(9) paid to victims by the manufacturers of those two drugs. One is compelled to enquire as to the necessity of excessive regulations of an industry already exercising caution for its own benefit, indeed its own protection.

It is essential that the regulators and the public recognise that people suffer and die from the lack of a new drug as readily as from the use of an unsafe drug. The former danger is subtle and receives little attention, yet the incentive in delaying the approval of new drugs is clear. For example, the decision-maker at the Food and Drug Administration(FDA) is faced with the possibility of erring in one of two ways. The first is to approve an unsafe drug. Resulting public and political attention would focus on the mistake and perhaps bring a Congressional investigation, the United States equivalent of Questions in the House.(10)

The other mistake is by excessive caution to delay or block an effective drug whose benefit to the public far outweighs a miniscule element of hazard. The result to the public welfare will be the same as that of approving the unsafe drug in terms of morbidity and death. Nevertheless, under the present system no one will know. There will be no public or political attention.

Alexander Schmidt, a former Commissioner of the Food and Drug Administration, has pointed out that Congressional enquiries into FDA approval of particular drugs were so numerous that no accurate count was possible, whereas there had not been one enquiry into FDA failure to approve a drug(11). The impact of these disincentives has fostered the continued emphasis away from encouraging the introduction of new drugs and in favour of cautious delay. What is desperately needed is that equal attention be directed at the effects of delay in approval of a beneficial drug as upon the negligent approval of a harmful one.

The innovation cost of this delay is subtle, yet significant. The discovery of new drugs by private industry accounts for the major portion of innovative work in drug development, responsible in 1970 for 82% of new drug discoveries(12). Investment in drug research and development is thus governed by business considerations. Such decisions are becoming increasingly risky, however, especially for the smaller concern. An annual investment by American drug firms of 1.15 billion dollars now yields approximately ten new drugs achieving FDA approval. This contrasts with the 60 or so generally approved annually in the 1950's and early 1960's.

It is estimated that only one in 10,000 pharmaceutical laboratory discoveries will reach the marketplace as an approved drug[13]. Considering this fact together with the substantial research and development cost required to bring that discovery along the journey towards the marketplace, it is not surprising that the number od companies introducing new drugs has dropped by over 50% in the past twenty years[14]. While some drugs generate a healthy profit for the manufacturer, the overall high drug development cost has caused many smaller concerns either severely to curtail their innovation activities or to eliminate them altogether[15]. A large pharmaceutical firm can absorb the tremendous development cost of a drug which does not receive approval; smaller concerns cannot.

Even among those "pioneer" companies which have continued to pursue the development of new drugs, the rate of return has been unpredictable. Many companies probably could have produced better profits by more safely investing elsewhere. A recent economic survey confirms that three quarters of new drugs developed by pharmaceutical firms fail to recoup their research and development cost, plus generate a profit[16]. In the final analysis it is the public which suffers most from the government disincentives imposed on the pharmaceutical industry.

The recent extension of general patent life in the United Kingdom from 16 years to 20 years will obviously be of benefit to the "pioneer" companies still engaged in innovative development. Yet the root problem of erosion of

patent protection during the approval process remains since the patent runs from the discovery, not from the time of approval. The net result is that whereas the manufacturer of a new cooker will receive a full 20 years of patent protection, the pioneer drug company will never be accorded the same reward for innovation.

Management has been forced to make some logical, yet difficult decisions. The result of those decisions is occasional unfortunate consequences for the public. The increased costs have prohibited a business decision to invest in the development of a drug benefitting a limited number of people. The financial return from such drugs, even when sold at high prices, would clearly be inadequate to recover the investment in development and extensive testing required for government approval.

Drug firms must also limit the number of discoveries which will follow the long and expensive path to an application for government approval. Since a highly innovative new drug often carries with it some substantial question marks and thus greater government scrutiny and consequently greater cost the incentive to develop new versions of conventional medicines is clear. The end result is that the public will find new drugs aimed at the largest number of potential users chosen for their likelihood to have clear sailing through the MC or FDA. The sufferer of sinusitis may benefit: the individual inflicted with an uncommon disease will undoubtedly suffer[17].

There is an alternative to drug research and development resting in the hands of business managers who are required to make decisions based on the profits to be derived from those decisions. That option is to achieve the same objective solely through government funding of academic or university laboratories. Such a solution would allow us to leave profits out of drug innovation considerations, and for this many would welcome the change. Yet government funding brings with it its own disastrous consequences. In addition to encouraging further growth of an already burgeoning bureaucracy, one must seriously consider the place such a vague item as drug research would occupy when the budgetary axe falls, as is now being witnessed in both the United Kingdom and the United States.

Politicians who recognise the political advantage of calling for greater drug regulation are often those who are quickest to attack the drug industry for generating profits. It must be seen that any attack on profits is also an attack on the most effective supply of innovative drugs which the world has. Nations which rely on alternatives to private industry for the development of drugs have contributed little[18].

The cost to the public of failure to approve beneficial drugs is not measured solely in terms of suffering or mortality. The consumer bears the burden of increased prices for drugs which flow from satisfying expensive heightened regulatory requirements, whether that cost is paid indirectly through the National Health Service by the British taxpayer, or directly by the American consumer.

Professors Wardell and Lasagna of the University of Rochester Center for the Study of Drug Development have kept a running account of the "drug lag" in the United States effected by the heavy burden of FDA regulations. The data which they have collected reveal the increasing delay in the introduction of new drugs into the United States market compared with the rest of the world, and the dramatic decrease in new drugs approved in the United States (19).

Their valuable work has been complemented on an economic basis by Professors Grabowski and Vernon of Duke University, who have presented the clear economic effects of oppressive regulation. In addition to their figures on total research and development, Grabowski and Vernon have also pointed out the centralisation of innovation activities in a very few concerns (20). Professor Peltzman of the University of California at Los Angeles, has demonstrated that the 1962 Amendments to the Food, Drug and Cosmetic Act, originally intended to protect the consumer economically from ineffective drugs, have instead led to a 5% "regulation tax" on American consumers' drug purchases (21).

Professors Reekie and Webber of the University of Edinburgh have presented similar figures for the growing economic effect of regulation in the United Kingdom, specifically the increase in cost and time required to bring a drug to market (22). Unfortunately, there has been only limited consideration of the effect of British drug regulation. This is no doubt due to the fact that the full effect of these regulations, which arose a decade after the American ones, is only now being appreciated.

There have thus been several such studies of particular aspects of the impact of regulations on the public from both sides of the Atlantic. What is now needed is an overall consideration of the various aspects of the problem - pharmacological, economic, legal and medical - in both the United Kingdom and the United States. The Authors have embarked upon a project to present such a perspective as a complement to those cited. For this exercise, initial funding has been provided by industry, administered by a trust dedicated initially to this purpose. The final objective is to produce a politically and socially acceptable and viable alternative to the present unsatisfactory system.

There are many possible alternatives available to remedy the current situation. First, a return to the former voluntary system. In view of the economic cost of the drug disasters of twenty years ago, it is difficult to argue that drug firms would not be sufficiently concerned for public safety in the absence of pervasive regulation. Second, some form of industrial policing of member's quality control and concern for safety. Whilst we recognise the danger of a small unscrupulous firm taking a quick profit and then disappearing, such a possibility could be anticipated by appropriate safeguards. Third, an ombudsman review of drug production, with the ombudsman provided with effective power when action is required. Fourth, some form of review committee overseeing the government bureaucracy, with an eye towards correcting the disincentives referred to above. Whilst these are only four

alternatives and have been mentioned only superficially, they need to be considered and developed. Urgent change is required in one form or another to institute such a remedy for the public benefit.

Due consideration must also be extended to the pressures which are rising for some form of international review board, whose task it would be to pass on new drugs. While such a system has the advantage of centralization, it also has the potential danger of requiring unreasonable evidence as a result of the cumulative effect of each member nation demanding its own demonstrations of safety and efficacy. On the other hand, greater mutual recognition of foreign testing and approvals would be of considerable benefit.

Perhaps the most dangerous effect upon the public of the modern regulatory climate, and yet most subtle, is the mistaken belief, instilled by the bureaucratic assurance of safety, that there exist "safe" drugs. The unfortunate result is that the regulators and the public have fallen into a pattern of encouraging each other's expectation of entirely safe drugs, rather than producing a more rational analysis and weighing of the risk and benefit inherent in all drugs. (A caution voiced by Dr. Cavalla and the participants in a symposium organized by Cavalla in 1980, which addressed the need for risk-benefit analysis in our drug supply[23]). Risk and benefit are inextricably bound together. The less the risk we are willing to tolerate, the less the benefit we may reasonably expect to obtain. The ultimate danger of a breakdown in this analysis is achievement of the lowest

common denominator, drugs which carry little risk but promise equally little benefit.

In answer to questions in Parliament in April of 1980, Sir George Young, the Under-Secretary of State for Health and Social Security addressed this most important aspect of the problem:

"This House, the media, the pharmaceutical industry and the professions carry a serious responsibility to ensure that the public accepts that modern drugs inevitably have risks as well as benefits, and that complete safety is attainable only at a cost which most of us would regard as unacceptable - that is, turning our backs on progress."(24)

Our intention is to adjust the present impact of disincentives at work upon the decisions of the regulators, to encourage the continued innovation of the drug industry, yet maintain a rational expectation of safety. Our Trust(25) has been established to help prevent the incipient failure of medicine to turn promise into performance in vital new therapeutic areas.

Mark C. Young
Doctor of Jurisprudence
&
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Consultant Clinical Physiologist

November, 1981

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Chairman,
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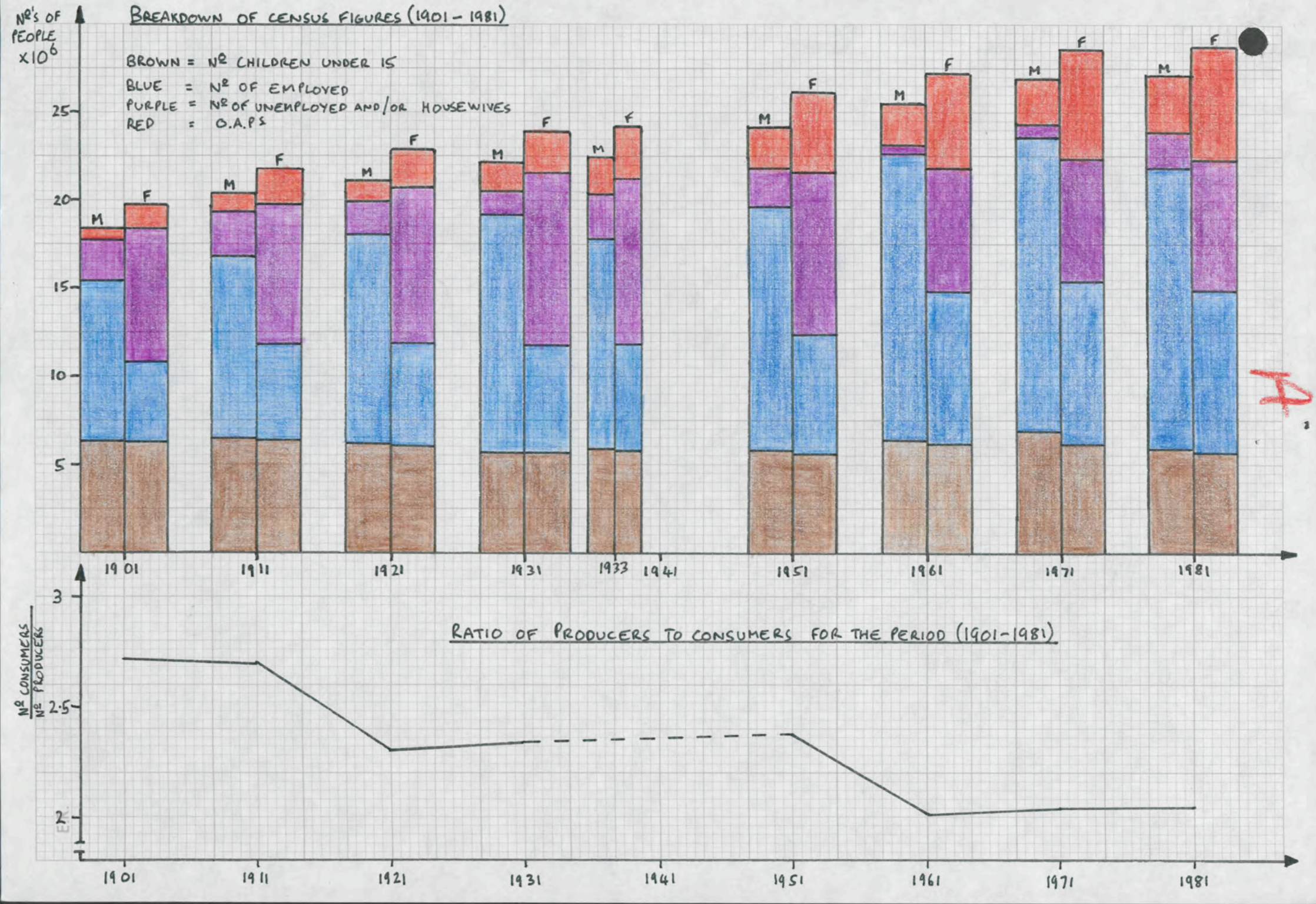
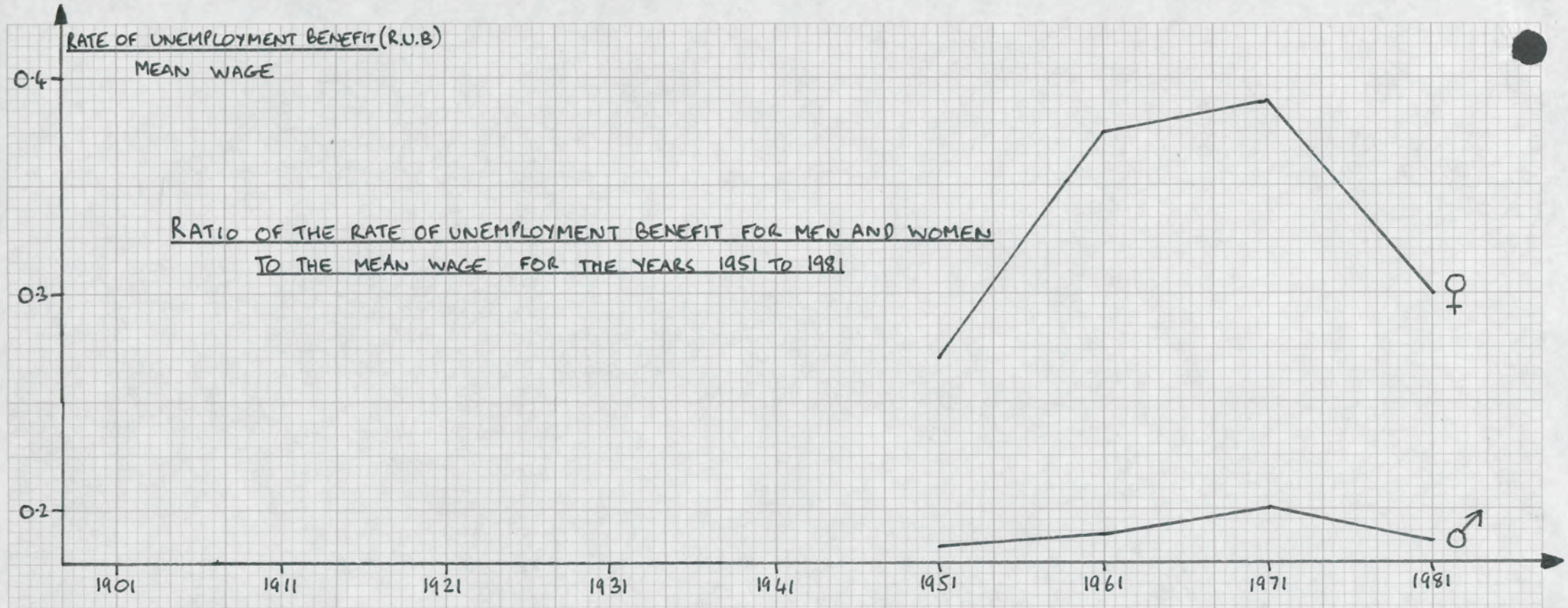
100 Hardy Street,
Hattiesburg,
Mississippi 39401
U.S.A.


Nr's OF PEOPLE x10^6
BREAKDOWN OF CENSUS FIGURES (1901 - 1981)
BROWN = Nr CHILDREN UNDER 15
BLUE = Nr OF EMPLOYED
PURPLE = Nr OF UNEMPLOYED AND/OR HOUSEWIVES
RED = O.A.P.S
25
20
15
10
5
M
F
1901
1911
1921
1931
1933
1941
1951
1961
1971
1981
Nr CONSUMERS / Nr PRODUCERS
RATIO OF PRODUCERS TO CONSUMERS FOR THE PERIOD (1901-1981)
3
2.5
2
1901
1911
1921
1931
1941
1951
1961
1971
1981


RATE OF UNEMPLOYMENT BENEFIT (R.U.B)
MEAN WAGE
0·4
0·3
0·2
RATIO OF THE RATE OF UNEMPLOYMENT BENEFIT FOR MEN AND WOMEN
TO THE MEAN WAGE FOR THE YEARS 1951 TO 1981
♀
♂
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1911
1921
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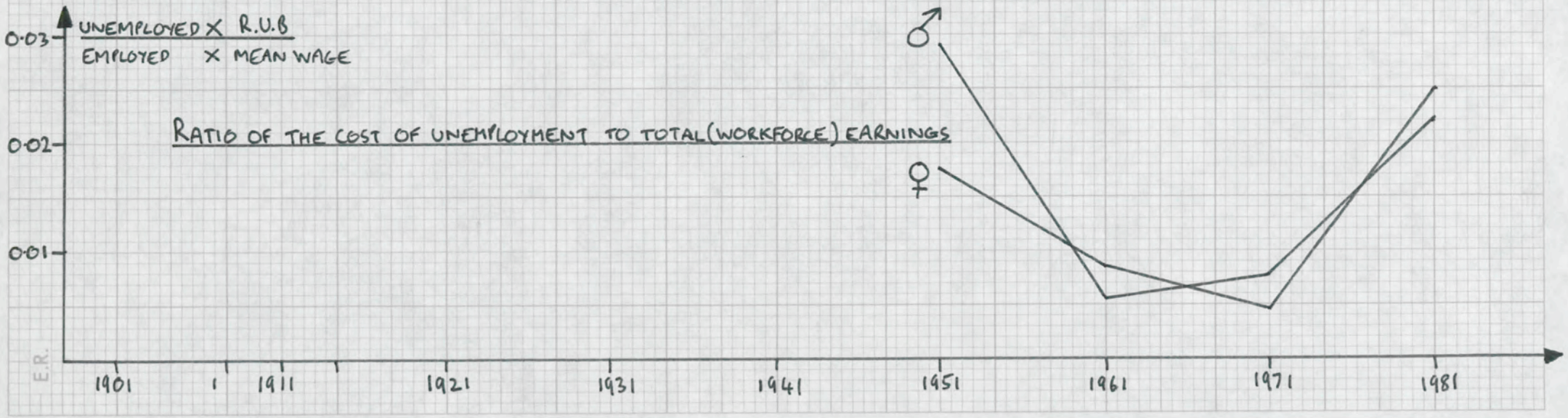
1981


UNEMPLOYED X R.U.B
EMPLOYED X MEAN WAGE
0·03
0·02
0·01
RATIO OF THE COST OF UNEMPLOYMENT TO TOTAL (WORKFORCE) EARNINGS
♂
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E.R.
1901
1911
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1971
1981

TABLE 1

YEAR	TOTAL POPULATION THOUSANDS	♂ POP. THOUSANDS	UNDER 15	15-65	65+	UNEMPLOYED	EMPLOYED	CONSUMERS / PRODUCERS	R.U.B / AV. WAGE
1901	38237	18492	6214	11493	784	2242	11548	2·73	
1911	42082	20357	6497	12895	965	2515	12930	2·67	
1921	44027	21033				2002	13 0	2·27	
1931	46038	22060	5643	14946	1471	1552	14790	2·34	
1951	50225	24118	5781	16089	2248	2213	13906	2·38	0·182
1961	52709	25481	6321	16782	2378	486	15994	2·01	0·189
1971	55514	26952	6873	17275	2804	618	15602	2·19	0·20
1981	55837	27132	5897	18011	3224	1918	14066	2·20	0·185

TABLE 2

YEAR	TOTAL POPULATION THOUSANDS	♀ POP.	UNDER 15	15-60	60+	UNEMPLOYED	EMPLOYED	CONSUMERS / PRODUCERS	R.U.B / A.V WAGE
1901	38237	19745	6206	11937	1602	10247	4732	2·73	
1911	42082	21725	6472	13339	1914	11432	5356	2·67	
1921	44027					11966	5701	2·27	
1931	46038	23978	5531	15497	2950	12055	6265	2·34	
1951	50225	26107	5544	15983	4580	476	7271	2·38	0·27
1961	52709	27228	6015	15858	5355	193	8863	2·01	0·375
1971	5554	28562	6515	15836	6211	106	8797	2·19	0·39
1981	55837	28705	5603	16657	6445	763	9323	2·20	0·3

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DEPARTMENT OF CLINICAL PHYSIOLOGY

NATIONAL HEART HOSPITAL

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TELEPHONE 01-486 0824
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Our Ref.

Your Ref.

5th August, 1983

Dr. L. Freedman,
Flat D,
21 Devonshire Place,
London W.1

Dear Lewis

Thank you for sending me a copy of Dr. Young's proposal and the relevant correspondence, also for the telephone call. His outline proposals are sound. I hope I can continue to contribute to G.E.C.'s lead in N.M.R.

No doubt with their outstanding success in the N.M.R. field, G.E.C./Picker have a matchless prize within their grasp, nevertheless they appear to me, as an outsider, to be at some risk of letting it slip away. I perceive three problem areas:

1. the production machines do not work properly;
2. the American end of the company unwittingly may jeopardise the future of the whole enterprise;
3. they do not seem to appreciate the potentially much larger market for the important second generation "contained field" machines conceived by Dr. Young.

Of course the production machines do not yet work properly, they are not "chinese copies" of the Hammersmith machine. That is the only practical clinical N.M.R. in the world. It is the gold standard against which all others are rated. Few will match it in the near future because the production magnets made by Oxford are not quite as good as the prototype magnet installed at Hammersmith. This constraint, however, applies to all N.M.R. manufacturers. In order to avoid further handicap Picker need to market machines which are exactly to Young's original specification and not "improved on" in any way either intentionally or by default, by those with no practical

experience or understanding on which to base developments. Every surgeon knows that when he adopts a new operation his results are subject to a "learning curve". We develop major new procedures here to a stage where the mortality rate is say 3% our careful imitators do well if they achieve a 10% mortality until they have learnt every detail, often taking over a hundred cases. Those who "adopt and adapt" end up with much higher mortality rates for an unacceptable period.

Basic surgical techniques are simple, as are the basic physical principles used in N.M.R. Major heart surgery and contemporary N.M.R. machines push both to the limit of our understanding. In N.M.R. even small changes in the design or the sequences used may result in a startling degradation in performance. Let me give an example: The Hammersmith machine uses a Data General computer programmed in Fortran and in Assembler. The production machines probably for sound reasons use a different computer. It should come as no surprise that the Fortran does not work in the same way when transferred. Assembler is not readily transferable, the programmes are probably best written de novo. This single change could put them back into the realm of software bugs in common with their competitors. The software Sword of Damocles now hangs over G.E.C./Picker as well as the rival firms. No one knows which bit of software will malfunction and under what conditions, a recipe for generating costly customer complaints. The problem may well be compounded by apparently small and insignificant changes in coil design, the methods of turning etc. M & D in Glasgow, the other British manufacturers of N.M.R. machines, are finding out these facts to their cost. Last month they showed me pictures nearly as good as those produced over five years ago by Peter Mansfield at Nottingham University.

One is always concerned about the manufacture of British designs in the U.S.A. I remember clearly the parallel position when Sir Godfrey Houndsfield was having problems with the CAT scanners manufactured by the E.M.I. subsidiary in the U.S.A. The Americans were unable to bring themselves to listen to the English engineers preferring to listen to local competitors who at that time had no working machine. There must be similar pressures on Picker to manufacture and market inappropriate machines. They have to resist the temptation to look for inspiration to G.E. and other American competitors.

It is fortunate for G.E.C. that G.E. and most of the major rival manufacturers have decided to produce N.M.R. machines which depend on the use of high magnetic fields with all their attendant problems. There is one notable exception, Bill Oldendorf in California, one of the pioneers of CAT scanning, has gone into partnership with a company to make a permanent magnet N.M.R. machine. His concept is not so many years behind Dr. Young's ideas for the new machine.

Through their American facility E.M.I. policies were influenced by the sales force rather than by Houndsfield and his group who knew what could work. Thus by management errors E.M.I. succeeded only in setting up an excellent training school in which their American competitors could learn our technology. It is fortunate that G.E.C. management is made of sterner stuff.

The longterm future of N.M.R. does not lie in costly high field machines intended for use in high technology hospitals. All the scientific evidence suggests that machines of the type proposed by Dr. Young will fulfil the real market requirements. Fashion favours high field machines capable of studying potassium and phosphorus. The use of a high field requires a corresponding high radio frequency. Such very short radio waves bend and refract, and cannot produce adequate spatial resolution. The facts are that:-

a) movie images are produced in Nottingham on a simple low field N.M.R.;
b) the best images in the world are produced at Hammersmith using low field;
c) our own heart gating work and our own preliminary blood flow studies show it is possible to visualise the coronary arteries with a low field (we have already produced velocity profiles showing not only amount of flow in the vessels but the characteristic of blood flow, all done with a low field).

For imaging, a low field is undoubtedly advantageous. Also it may soon be possible to study potassium and phosphorus in a low field using physical effects which are not yet fully explored.

Young's proposed design overcomes the three main objections to N.M.R. as a new diagnostic technique, a safe practical X-ray replacement and a machine useful for population screening. It will be cheaper to buy and run, there will be no biohazard from stray field and patients will not be pushed into a claustrophobic tube. It does not surprise me that Dr. Young has come up with a potential winner. He has a track record of sound ideas and the ability to make them work. There are other powerful reasons for adopting his proposed design with all expediency. Magnet technology is not quite as simple as it appears and Oxford Instruments are already unable to meet the demand for high quality magnets with a homogenous field. The proposed G.E.C. machine takes the magnet technology out of the hands of Oxford back into G.E.C.'s own areas of expertise. The power division of G.E.C. is probably second to none in the design of the kind of magnets which Young's machine needs. The type of magnet proposed is of course more stable and less susceptible to interference than those favoured by most firms.

In fairness I should make it clear that I have an axe to grind as a proponent of this mahcine. As you (and Lord Weinstock) know, for a number of years I have been trying to crack the problems of heart disease by detecting it at an early stage and monitoring its progress under treatment (see appended note which was prepared for a patron of the C.O.R.D.A. charity). A practical, easy to run N.M.R. machine, combined with a few other non-invasive instruments (one of which I have created to work in association with N.M.R.) gives us the opportunity to look at the normal population say every 9 months. Anybody who is deteriorating will be spotted; any patient who is treated can be repeatedly assessed to see if the treatment is working. This use of N.M.R. is far more important than its immediate role in replacing equipment and techniques aimed at the management of end state disease. The potential new market for a combined N.M.R. non-invasive set up is of course unknown but must exceed any market explored so far. There are a number of countries which have decided, or been forced to leap-frog the present inefficient expensive and unrewarding management of cardiovascular disease. In the West we wait till more patients than we could possibly cope with

have end state disease and then manage what we can, at enormous expense, with heroic surgery. (The coronary vein graft is now the commonest operation in the United States having overtaken the old favourites of hysterectomy and appendicectomy.) Other countries have decided to wait until prevention of cardiovascular disease is possible (this is dependent on early diagnosis). Nearer to home, the charity C.O.R.D.A. is dedicated to detection, protection and prevention. Its Board of Management and Scientific Advisory Council have been quick to see the value of N.M.R. in its carefully focussed and vital area of interest. I hope the charity will be supported adequately in its endeavours which will of course be helped by the availability of practical N.M.R. machines.

This rather long letter is of course an incomplete summary of a complex situation. If it would be helpful I am prepared to amplify any specific points.

If G.E.C. make the current machines work like the Hammersmith installation, help us apply N.M.R. to cardiovascular disease (54% of all disease) and show determination to develop the new machine with all haste, the time has come to buy all the G.E.C. shares you can afford.

Do not forget you are welcome here at any time to see what is going on.

All good wishes.

Yours sincerely,

Donald.

Donald B. Longmore, FRCSEd
Consultant Clinical Physiologist

FUTURES

Benign management or malignant bureaucracy?

If the British medical service could settle on a coherent plan for its future, worked out in fair detail, it would command and lead the support of a biomedical and biochemical engineering industry that would put the rest of the world in the shade. Why do we persist with the present anarchic free-for-all?

Longmore

Donald Longmore is consultant physiologist at the National Heart hospital, London, and **Malcolm Ross-Macdonald** is a freelance writer

Ross-Macdonald

One easy way for a TV producer to gain a reputation for making honest, hard-hitting documentaries is to turn his camera lenses on any aspect of the British medical scene. From top to bottom he will find plums ripe for picking: the inadequacy of the Ministry and its ad hoc approach to planning; the ancient autarchy of the part-time consultants; the dwindling role of the lone GP; the bitter discontent of junior doctors and nurses; antediluvian buildings kept going at disgraceful cost; and social euthanasia that passes for care of the aged and the mentally inadequate; our endless waiting lists for operations that are life-enhancing rather than life-saving; our absolute dependence on overseas doctors and nurses; our charmingly stochastic methods for financing research; the approaching collapse of the whole service; there seems no end. Even the successes—the new hospitals, the community care centres, the units for specialized therapy—even these can be attacked as "far too little, almost too late".

Such piecemeal attacks on the structure of medicine are, in effect, doubly pernicious. In the first place they create dissatisfaction—among medical workers who know they are true, among the public who feel they ought not to be true, and among administrators and planners who (in the short term anyway) know why they are true. In the second place they narrow the focus on to particular evils in so dramatic a way that a rational discussion of the *total* structure, the structure that permits the evils, becomes too abstract to command attention. The dissatisfaction cannot be met nor can the discussion be attempted as long as we are distracted by such piecemeal scandal.

Many an empire builder, military and industrial, must have faced equally despairing situations: occupied countries or taken-over companies swamped by day-to-day problems, unaware both of their place in the grander design and of their pathway toward it. Medicine is very like that: a ramshackle empire run by moderate dissidents and foundering for lack of vision. Yet the techniques for transforming such situations are already well established in industry and could quickly be adapted to make medicine more fitted to our needs in the final third of this century.

Wise industrialists have learnt to begin by asking not "where do we *want* to be two decades from now?" but "where would it be *possible* for us to be . . . ?" From a survey of the possible futures they pick those that currently suit their purposes best and they start making the necessary changes—in organization, staffing, training, investment, reserves, mergers, research . . . and so on. From time to time they review their original decisions, modify them if necessary, and check their current progress toward these rationally chosen and rationally modified goals. Medicine could be very like that, too.

Those who care about the future of medicine are all too apt to ask "where-do-we-*want*-to-be" questions—and, of course, to get pie-in-the-sky answers. We should begin by asking "what would it be possible for us to achieve, say, between now and the end of this century?" In fact there have already been numerous delphic studies of the futures in medicine, bioengineering and fundamental biology. We do not lack for basic, serious, and well-informed prediction.

As a next step we could admit: 1. that not all the advances will be simultaneously within our resources—though, of course, we must include on the credit side of the ledger the often neglected bonus of medicine: the numbers returned to productive work, whose efforts repay the capital invested in therapy; 2. that some may, within the 30-year term of a review, be actually harmful—for example we may exacerbate the effect of the continuing rise in world population; 3. that some may contain hidden perils (one thinks particularly of genetic medicine and iatrogenic disease) and should be applied on a limited scale in last-resort situations even though one could think of more general outlets; 4. that the return on some, however defined, may not yet justify the human and financial investment; 5. that medicine, properly organized, will have important regulatory roles that it cannot now command—in education and industry, for instance.

This brief list by no means exhausts the major considerations, but it does show the sort of sieve we could apply in our "first-order" decisions about the future. None of them involves specialist training of any kind; all concern the scope and quality of medical services. They could, and should, form the basis of the widest possible public debate, both formal and informal. Of course, popular TV and

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many papers will reduce the debate to the "computer - will - say - say - 99" and "pill - will-determine-sex" level; but as long as this is overlaid with more serious discussion in the quality media and as long as the main participants in the debate argue from informed positions, we will achieve most of the necessary decisions. The debate could range for years, though one would hope that major decisions will be taken early rather than late.

Such a debate would lead to a clear ministerial directive embodying as coherent a view as possible of the likely future. The debate need not—indeed, could not—end there; like the wise industrialists, we would have to review our decisions in the light of progress and reverses both here and elsewhere. Nevertheless, such a formal statement of aims would illuminate every part of medicine. It would make us the most precious gift of all: time. Time to re-educate. Time to make all the necessary changes—in building, investment, research, reserves and, above all, in attitude.

The debate would have to be accompanied by a very thorough "second-order" debate, which, by its highly technical nature, would be confined to the profession and its administration. To change the terminology slightly, the first-order discussions constitute "feed-forward"—an organized search of the terrain yet to be covered in order to discover the best goals and optimum paths. The second-order negotiations constitute "feedback". It is at this level that we construct systems for monitoring our current progress—a bland-seeming statement that, in fact, proposes the most radical reform of medicine ever contemplated. Every researcher, every GP, every therapeutic unit, every administrative department, would find his or its work related to first-order goals.

It is impossible to convey the sense of invigoration that can follow when every individual can relate his effort to the whole. Many who work in industry must know the feeling: researchers, workers, and managers in moribund companies taken over by dynamic firms with a clear vision of the future.

But, as the strikes that sometimes follow such takeovers show, there is a price to be paid by those whose line of work or whose performance fails to match that vision. Every medical worker, unit, and administration will find his or its performance checked—after all, that is precisely what feedback means. A medical degree would then be seen in its true light: a passport to continuing education in both general and specialized medicine. (At the moment we rely almost exclusively on random experience gained under stress and often in an enervating environment.) It is at this level that the success or failure of the new system will be determined. We all know of organizations that chose impeccable goals but were rather casual about their progress. We have no choice but to be ruthless with ourselves; if we are not, the ineluctable laws that govern complex systems willl combine to cheat us of our goals anyway.

In stressing the internal advantages to medicine we must not overlook the far greater advantages to the community. By removing medicine from the bear-pit of politics, where its largely unplanned direction is at the mercy of every secret power group, every accusatory splash in the mass media, we could bring an urgently needed stability and sense of overall purpose. In such an atmosphere the quality of care would vastly improve. To show this in particular and concrete terms let us consider just three very specific questions about the service and show possible answers to them today. Then we will look at possible answers under the new system.

Q.I Why is care of the subnormal and the chronically mentally ill so inadequate?

1. Because the Ministry has apportioned budgets in such a way as to starve mental medicine of funds.
2. Because mental medicine does not offer prestige and awards comparable with other fields—so the service is weighted by the less motivated who can easily get shoved to the back of the queue.
3. Because people don't care enough to put the pressure on the government.
4. Because our economic priorities do not allow it to be better.

Q.II Gastrectomy for cancer and the transplantation of kidneys, heart and liver are all palliative operations in that they may prolong life, may even return a patient temporarily to help the economy—but even where they do not, they can still turn a distressing and painful death into one far milder and more pleasant. Is our present apportionment of money between these therapies reasonable?

1. Gastrectomy has been established for almost a century, and although its success rate is no better than that for transplantation it would be wrong to compare the established with the experimental.
2. We do not know.

Q.III Many millions are spent on medical and related biological research. Unaccountable millions more go into the development of biomedical machines, chemicals and systems. How cost effective is this vast expenditure?

1. The industrial expenditure, being subject to market forces, is fairly effective. But research funds handled by government, universities, institutions, and charities are scrutinized by accountants looking for fiddles—not be investment—manager types looking for return. Cost-effectiveness is bound to be low.
2. Research as such is pretty effective—Britain has a good record here. It's the industrial investment that is poor. Industry in America, Sweden and Germany is far better at exploiting biomedical research and turning discovery into currency—earning hardware.
3. Effectiveness doesn't come into the picture. Department A gets money out of charity X with the voting support of faculty B. Faculty B, of course, will rely on department A next time around. It sounds terrible but fortunately they're all responsible people and so it works pretty well. Anything more formal would only fossilize the prevailing state of anarchy.
4. We do not know.

These three specific questions can be taken to stand for large and important areas of the service. The first question, suitably extended, covers facilities, conditions, rewards. The second question covers the benefits, however measured, derived from all forms of treatment. Question three covers the effectiveness of our investment in the future. The answers, all of which we take to be honestly (even if a little cynically) held by some important section of the profession or the public, reveal the thoroughly unsatisfactory state of anarchy now prevailing.

How would we be able to answer these same three questions under the new system? QI poses a difficulty because, in our view, mental welfare could not possibly come out of a rational plan as badly as it now comes out of our free-for-all. But, for the sake of the exercise, suppose the question were still relevant, we would be able to reply:

> Because in a long and wide ranging debate two years ago, a debate in which you could have—may have—played a part, the consensus came down in favour of other goals. Nobody enjoyed such a decision but the alternatives and their costs *were* made clear, and they proved even less palatable.

To QII we could say:

> By the criteria provisionally accepted two years ago the benefits of therapy A have been overestimated in relation to those of therapy B. True they are for different ailments, and so are difficult to compare; in fact, it is clear that the accepted criteria already need modifying. Until we have our new yardsticks we are not proposing any changes. But if they show the same disproportion we shall certainly make changes in our promotion of these therapies.

Obviously we could have made a different answer; This one was chosen because it reveals that the new system must be both flexible and adaptive.

For QIII we could say:

> Industry and other sources of R & D grants now know the expected direction of medicine for the next 30 years. It is gratifying to see how quickly they have responded to the lead. Many have formed joint committees with one another to cut out wasteful overlap and promote competition. For instance, there is now only one British researcher working on "rare blood groups in the Bamingui and related tribes", while over 30 co-ordinated groups are now studying various aspects of haemodynamic regulation—precisely the reverse of the situation four years ago. In practical ways, too, they are getting for more investment conscious. For instance, Charity Y did a survey of all the machines bought by researchers out of Y grants. They found almost half of it—£84 000 worth—was hardly used. The researchers had been quietly holding on to the stuff for fear their next grant would be cut. At least £50 000 worth of this machinery has since been redistributed among existing grantholders—who actually needed it. These are just two of hundreds of ways in which the funding bodies are enabled, by the new system, to double or treble our return on each £1 of investment.

This answer has enabled us to introduce the clinching argument in favour of rationalization in medicine: economics. We are a rich and ingenious nation with excellent traditions in biological and medical research, and electronic and mechanical design. We have on paper and could have in reality a centrally organized medical service. If that service could produce a coherent view of its future, worked out in fair detail, it would command and lead the support of a biomedical and biochemical engineering industry that would put the rest of the world in the shade. Just as the town of Rochester, Minnesota, now lives off the fall-out from its prestigious Mayo Clinic, so the entire bioengineering industry in the United Kingdom thriving in an assured market with a known future, could undersell the world and make medicine one of our biggest earners of foreign exchange.

That last statement sounds extreme—until we remember that mankind is approaching three gargantuan crises, any one of which is larger than any crisis in our history: population, urbanization and global pollution. Medical remedies, medical advice, medical hardware, medical planning—all will play a central role in preventing these crises from engulfing us. Medicine as at present organized—not just in Britain but throughout the world—is ill-fitted for such a role. For different historical reasons no country is so well-poised as Britain in the 1970s to make the necessary changes. We have the skill; we have the resources. We have the stick—that is, the knowledge that failure would widen and deepen our present malcontent. Let us hope we do not lack the carrot—the will and the vision.