An ethical dilemma

Availability of antiretroviral therapy after clinical trials with HIV infected patients are ended

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Professor Cleaton-Jones describes the dilemma faced by South African ethics committees asked to approve clinical trials of treatments for HIV infection. We asked a member of a patient advocacy group, clinical trial coordinators, an ethicist, and a representative of a drug company to give their views

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BMJ 1997;314:887–91

Guidelines on good clinical practice for drug trials clearly state that ethics committees must ensure that the safety, integrity, and human rights of the subjects participating in a particular trial are protected.[1] Fundamental concepts are informed consent and risk or benefit to participants in a trial. For many clinical trials, ethical clearance is straightforward but those involving people infected with HIV generally are not.

Here, we are dealing with a condition that is presently incurable with variable progression, drug treatment is expensive, and emotions run high. These matters are common to all countries, but those of us living in Africa have an added burden—Third World conditions and an estimated 13 million people infected with HIV, usually from heterosexual sex.[2] In South Africa the most recent published results for the fifth unlinked anonymous national HIV survey show that HIV infection in women attending antenatal clinics has risen from a national average of 1.35% in 1991 to 7.57% in 1994.[3] In some parts of the country the rate is as high as 14.35% and is increasing.[3] Because of a shortage of resources, antiretroviral drugs for treating HIV are not provided by South African public health services: these are available only in the private sector at great expense.

Given this high prevalence of HIV it is understandable that multinational drug companies are attracted to carrying out trials in our country, with its combination of a large infected population and proved medical expertise. Ethics committees are currently receiving trial protocols for combinations of drugs from such companies. All protocols provide for the free supply of trial drugs for a specified period, usually two to three years, for patients satisfying the inclusion criteria. The trials are well designed and comprehensive, but there is no guarantee that the drug treatment will be continued beyond the end of the trial. Therein lies the problem. South African ethics committees use guidelines on ethics for medical research provided by the South African Medical Research Council.[4] Comprehensive as these are, they do not solve the following dilemma.

What is the responsibility of a trial sponsor to a trial subject who responds to treatment that will not be available after the end of the trial? With most diseases this is not a problem since alternative treatments are available. However, when no other treatment is available to trialists what should be done? If a patient infected with HIV responds to the test drugs, may one ethically withhold the drugs at the end of the trial, thereby depriving the person of benefit? My committee's opinion up to the present has been that it is not ethical to do so and that such trial subjects must continue to receive the antiretroviral treatment after the trial ends until they cease to benefit or are enrolled into another trial. Naturally, most companies have not received this opinion with joy. Their argument is that informed consent, which clearly states the length of a trial, takes care of the problem. In theory this is correct, but South Africa has large numbers of people insufficiently educated to understand the implications of what they are consenting to.

In early trials, when monotherapy was the rule, many companies complied with our requirement, but combination therapy has altered company policy. Companies often must purchase another manufacturer's drug to use in conjunction with their own. As a compromise, companies are generally prepared to provide their trial drug until it is no longer under development or is commercially available or they will provide zidovudine alone. Since combination therapy is the current optimal treatment,[5,6] can ethics committees allow patients to revert back to a less effective treatment? Furthermore, even if a drug becomes commercially available, is it ethical to halt treatment knowing that neither the health service nor trial subject can afford it?

Investigators fall into two clear camps. Some will not undertake trials unless there is an arrangement for their patients to receive drugs long term or to be enrolled in subsequent trials. Others know that their patients would normally receive no treatment at all, so

two to three years of treatment is of some benefit at least and may buy time for future breakthroughs.

A further complication is the variation in policy of ethics committees. Our committee, established in 1966, is the oldest and most experienced in South Africa and is known to be conservative. Protocols not accepted by us, we know, have been readily approved in the private sector or at other institutions. To be fair to all concerned we have sought personal opinions from research coordinators in HIV trial groups in Canada and Australia. In Canada continuation of drug treatment beyond the trial is expected, but this is simpler because a drug company can continue to supply its own drug to be added to the antiretroviral treatment available from the public health services. In Australia it is accepted that drug companies are unlikely to provide long term treatment, and colleagues there believe that monotherapy, with at least a double nucleoside, after completion of a trial is acceptable when no other treatment is available.

Realistically, the level of illness required for inclusion into trials is such that many subjects may not survive past the trial period. Surely, agreement can be made on a response to the trial drugs so that only those responding may continue treatment; those not responding may be taken out of the trial to free resources for the responders beyond the trial.

This has been debated at length in our committee with investigators, trial sponsors, and potential subjects. The most strident voices of all are those of patients infected with HIV, who feel that the decision to participate in a trial is theirs alone, not that of an ethics committee acting in a paternalistic manner. But ethics committees have to ensure that patients are not exploited and that benefit outweighs risk.

1 CPMP Working Party on Efficacy of Medicinal Products. *Good clinical practice for trials on medicinal products in the European Community*. Brussels: Commission of the European Communities, 1990. (9148/90-EN.)
2 Quinn TC. Global burden of the HIV pandemic. *Lancet* 1996;348:99-106.
3 Fifth national HIV survey in women attending antenatal clinics of the public health services in South Africa October/November 1994. *Epidemiol Comments* 1995;22:90-100.
4 *Guidelines on ethics for medical research*. Revised edition. Tygerberg: South African Medical Research Council, 1993.
5 Volberding PA. Improving the outcomes of care for patients with human immunodeficiency virus infection. *N Engl J Med* 1996;334:729-31.
6 Schooley RT, Ramirez-Ronda C, Lange JMA, Cooper DA, Lavelle J, Lefkowitz L, *et al*. Virologic and immunologic benefits of initial combination therapy with zidovudine and zalcitabine or didanosine compared with zidovudine. *J Infect Dis* 1996;173:1354-66.

Strident, but essential: the voices of people with AIDS

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In the developed world the voices of advocacy groups for people infected with HIV have long been strident. This stridency arose from the behaviour of drug companies, which, together with physicians, were controlling access to, and knowledge about, antiretroviral treatments. Many such groups have a good understanding of the required protocols for drug trails and the available treatments which may prolong lives.

In South Africa the community of people infected with HIV has yet to raise its strident voice. Its stand is largely tentative, unarticulated, and mostly ignored. As a member of NAPWA—the National Association of People Living With HIV/AIDS—I am part of the growing community of HIV infected people working to change this. I attended a meeting of the ethics committee chaired by Professor Cleaton-Jones at which a proposed trial protocol was being evaluated. It was the first time that a member of an advocacy group had been present. It is, as Cleaton-Jones said in his article, our "safety, integrity, and human rights" which are being decided on, and we must have a voice and be heard in the debates about which trials will be supported and undertaken and which will not.

Yet, I found it difficult—because of the diversity of views and of our ignorance about the debate about treatment—to confidently articulate the views of my community on trials of drugs for treating HIV. There is a tension between investigators and clients with regard to these trials. To researchers the trials are often seen as experiments and we are research subjects, whereas to people like myself the trials are something far more important: they are seen as treatment rather than research—and are often the only way in which we in South Africa have any access to treatment—as well as being a source of hope that the new drug combination will prove to be the "magic bullet." This tension is particularly acute because the quality of medical care is highly variable and there is little recognition from the government or the drug companies of the need to make effective treatments available at a price that most people could afford. The final tension is, as Cleaton-Jones points out, what happens to the research subjects once the trial is over.

Although there is a strong feeling that it is unethical to allow people to enter trials when the treatment will cease after a specified time, many people feel that access to limited and potentially beneficial treatment is better than no treatment at all. There is always the hope that a way will be found for beneficial treatments to continue. Both these views are debated in the community of HIV infected people. This is essential so that when members of our community are asked to give "informed consent" they have been well prepared, given Cleaton Jones's recognition of the inability of many researchers to explain the protocols clearly and effectively to those "insufficiently educated to understand the implications of what they are consenting to."

These tensions need to be resolved. Our voice must be heard, not in a patronising and glib way, but in a manner which indicates a real commitment to seeing our concerns as genuine worries rather than irritating stridency. Of course, the widely divergent community of HIV infected people at present allows for investigators to exploit our differences and lack of detailed knowledge to engage some sectors but not others. Cleaton-Jones's article highlights the need for NAPWA to develop a

clear and well articulated stand on trials that all people infected with HIV will feel confident in supporting.

People infected with HIV have a right to decide whether they participate in trials. Investigators and drug companies have an obligation to share their knowledge and debates about treatment with the community that they wish to enrol for further research. Failure to do so will ensure that HIV infected people remain suspicious both of their intentions and commitment to finding an affordable treatment from which we can all benefit.

With special thanks to Mary Crewe for support and encouragement over the years.

Drug companies have a duty to continue treatment

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There is growing interest from the pharmaceutical industry to sponsor clinical research and development in the developing nations of the world. This expansion is a direct response to the critical need for companies to reduce their development times, thus extending the time over which a product might make a financial return on investment. In supporting such research and development, industry plays an important role in developing further the healthcare systems of selected countries. Research supports the development of infrastructure and enhances the training and experience of healthcare professionals. In return, data that define the potential clinical value of new treatments are generated.

This reciprocity is threatened by problems such as the ethical dilemma identified by Professor Cleaton-Jones. The continued provision of study treatment to participants of a trial, as deemed necessary by the treating clinician, after the trial has ended is clearly a complex issue. Resolution will require the productive interaction between various different groups with diverse interests. The basis for such discussions is often obscured by the emotive nature of the disease. It is vital to further progress that a framework is established within which specific detail can be resolved. It is equally imperative that clinical research continues in countries of the developing world. This is particularly important for diseases such as HIV infection and AIDS, where even modest benefits in relatively small numbers of people may have a substantial impact on affected communities.

Where there is enthusiasm for clinical research and use of experimental treatments there should be few hurdles to prevent doctors and their patients from making informed decisions that are relevant to their circumstances. Virtually all nations have guidelines or regulations describing the ethical requirements of conducting clinical research in human subjects. It is important that such national autonomy is preserved and nurtured. Central to every set of guidelines is the obligation of adherence to the Declaration of Helsinki, particularly the sections relating to conduct of medical research in humans.[1] The Helsinki declaration is appended to almost all industry sponsored protocols as a binding framework for conducting clinical trials.

More importantly, regulatory authorities around the world (including the Food and Drug Administration and the European Agency for the Evaluation of Medicinal Products) require that submissions made to them in support of a licensing application are composed of data from clinical studies that fulfil the requirements of the Helsinki declaration. Two sections from the declaration are relevant to the issue identified by Cleaton-Jones:

- In any medical study, every patient—including those of a control group, if any—should be assured of the best possible diagnostic and therapeutic methods (section II, para 3).
- In the treatment of the sick person, the doctor must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, re-establishing health or alleviating suffering (section II, para 1).

In our view, these explicit statements demand the continued provision of antiretroviral therapy. This should be, at a minimum, to the standard of care identified by the protocol. In studies of antiretroviral therapy for HIV infection, clinical judgment can be supported with great accuracy by measurement of plasma HIV load and CD4 cell counts. Any industrial sponsor that does not make substantial efforts to satisfy these requirements in countries where there is restricted access to established treatments should recognise that its studies might be regarded as unethical. As such, any data generated from the studies would be unusable in support of a licensing application. This represents a greater ethical dilemma since the research would have no utilitarian value.

Companies that go to countries in the developing world in order to have access to large numbers of HIV infected people who have never been treated must be under an obligation to conduct the study as they would in countries of the developed world. Clinical research in countries of the developing world must not be seen solely as a cost saving mechanism. Clearly, there will be a financial penalty to companies that provide continued access to treatment for the participants of trials, and this will be amplified if drugs from other companies must be purchased. However, companies that make this relatively small investment may be rewarded through the generation of data that increases their product's market lifetime by reducing development times.

The National Centre in HIV Epidemiology and Clinical Research is supported by the Australian National Council on AIDS through the Commonwealth AIDS Research Grants Committee.

1 The declaration of Helsinki. In: *World Medical Association handbook of declarations.* France: World Medical Association, Ferney-Voltaire, 1964: 48-51.

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A case for goodwill

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Professor Cleaton-Jones nicely sets out the difficulty facing research ethics committees. It seems quite obvious that drug companies should be asked to guarantee the ongoing supply of the full regimen of drugs used in a clinical trial for just so long as those drugs are proving to be of benefit to the particular subjects. But what if a drug company refuses and guarantees the supply only for the period of the trial? Should the ethics committee accept these terms, or should it make the ongoing supply a non-negotiable condition of approval of the trial?

If drug companies were inanimate objects, committed by impersonal forces to unalterable courses of behaviour, then there would be no real ethical difficulty. We would then simply face the facts of life and accept the less than desirable terms of the trial, hoping for whatever benefit the drugs might provide to the subjects over the limited period. Better something than nothing. It would then simply be for the individual patients to decide whether to participate in the trial on those terms (for, of course, every effort would have been made to ensure that the candidate subjects were genuinely fully informed about the choice open to them).

But drug companies are not inanimate objects: they consist of people who form attitudes and choose courses of action. And so an ethics committee can ask a recalcitrant drug company to think again. On what basis? On the basis of a fairly small amount—surely a requisite amount—of goodwill. For what is at stake here is the kind of attitude that the drug company takes towards the subjects from whom it seeks to profit. In a place like South Africa, to withdraw drugs from patients with AIDS that are proving to be beneficial to them would be to leave them cruelly dangling—with no alternative means of receiving the benefit and facing death instead (or, at least, a worse death or one that comes sooner). A policy that deliberately allows this to happen to research subjects smacks of a callously exploitative attitude towards vulnerable people—vulnerable because their illness is all too likely to make them desperate to join any trial that might offer them any benefit.

By contrast, a drug company which undertook to maintain the supply of beneficial drugs would display an attitude of appropriate respect and care towards the subjects—treating them, not as objects to be disposed of when their usefulness has been exhausted, but as people who are entitled both to the respect due to coworkers in a scientific project and to the properly sensitive care due to patients who are seriously ill. Indeed, public knowledge that the drug company works with this attitude would hardly do the company any harm. Goodwill has always been a commercial as well as a moral category.

Moreover, a hard headed scrutiny of the possible outcomes of a trial seems to indicate that such goodwill would require little real altruistic sacrifice by the drug company. For, in broad terms, there are only two possible outcomes of the trial: either the drugs provided benefit for the subjects or they did not. If they had not been beneficial they would be withdrawn at the end of the trial, and the drug company's guarantee of a possible indefinite supply would, in fact, have committed it to no cost beyond the strict costs of the trial. On the other hand, if the drugs had been beneficial the company's undertaking would have committed it to further costs. But in this case, the very discovery that the drugs are beneficial would also, presumably, entail considerable future profit for the company. (Foreseeable profit is, after all, why the company is performing the trial in the first place, and a genuinely effective therapeutic drug for HIV infection would surely meet a very ready market.)

Thus, in these broad terms the possible outcomes are such that the undertaking we would ask for would commit a drug company either to no extra costs at all or to further costs that would be offset—presumably very satisfactorily—by profit.

For these reasons, I find it hard to take the drug companies' protests very seriously.

A partnership to resolve the conundrum

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As Professor Cleaton-Jones points out, ethics committees protect patients from exploitation and ensure that the benefits of a clinical trial outweigh the risks. However, ethics committees are not the only group charged with this responsibility. A drug company's medical division also takes responsibility for patients' welfare during a clinical study, and patient advocacy groups play an increasing role. In other words, drug companies now work alongside clinical investigators, ethics committees, and patients' groups. Not only does this enhance a study's scientific credibility, but it helps to resolve problems facing ethics committees.

Nevertheless, the industry recognises that there are inequalities. In Britain it is relatively common for subjects enrolled in a trial of a new treatment for HIV infection to continue to receive the drug from the end of the trial until the drug's commercial launch. In some parts of the world, including South Africa and Brazil, this may not be the case. In some developing nations the system seems to work on the assumption that a

short course of treatment is better than nothing. As a result, drug treatment does not continue after the end of the trial. In my view, however, drug companies are under a moral obligation to continue drug treatment in certain circumstances.

Against this background, patient advocacy groups could argue that legislation should be introduced to ensure continuing access. However, legislation could stifle scientific creativity. Some companies run small scale, pilot trials to investigate specific, somewhat experimental issues. Companies might be more reluctant to proceed if they were under a legal obligation to ensure continued availability of what might be very expensive treatment.

The way forward is to forge alliances. As an industry, we have traditionally worked alongside clinical investigators. Now drug companies are increasingly working with patient advocacy groups. In many cases advocacy groups' main complaint concerns the traditional lack of consultation rather than specifics of the study. Moreover, trials rely on the goodwill of the subjects. By talking to advocacy groups, drug companies can avoid getting a bad reputation by word of mouth that can make recruitment difficult.

Drug companies, ethics committees, and advocacy groups may not always agree. Indeed, their views may be almost diametrically opposed. However, discussion allows each side to appreciate the others' positions and approach a compromise—if not now then possibly in further studies. Nevertheless, scientific credibility and economic vitality cannot be held hostage to political correctness. In a recent study Roche was able to persuade a patient advocacy group that its design was incorrect. Moreover, clinical trials need to address several marketing considerations—not least the need to rapidly market the results of our innovation and retain the commercial benefits of our intellectual property. However, most of the concerns of patient advocacy groups and ethics committees can be overcome through careful planning.

To fully engage in an informed debate about clinical trials and a drug's availability after a trial, patient groups need to understand the medical issues. In Britain, particularly, the general public has a poor understanding of human biology. Patient advocacy groups recognise the educational gap, and most advocacy groups for HIV infected people are able to call on the expertise of at least one medical practitioner. In some ways, trials of treatments for HIV infection are a model of clinical trials in the future. Patients' groups are becoming increasingly vocal about other diseases—such as breast cancer and diabetes. Continuation of treatment after the end of a trial may emerge as an issue in these areas. I believe that partnership is the way to resolve the problems facing drug companies, ethics committees, and patient advocacy groups. In the final analysis we all work to the same end—improving patients' quality of life.

Surgical training: an objective assessment of recent changes for a single health board

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Abstract

The reduction in doctors' hours and the introduction of specialist training have reduced general surgical training by 60%. This study assessed the implications for a single health board. A questionnaire listing 13 representative operations was sent to 44 trainees and 52 trainers to determine the number of operations a trainee should perform. The total number of operations required for training was compared against the total actually performed across the health board. Operating times for five representative operations were audited prospectively. Trainers and trainees recommended a similar and conservative number of operations. The total number of operations available for training (4913) was 38% less than the number recommended (7946). Trainees required 50-75% more operating time than consultants. To increase the proportion of operations undertaken by trainees from the current 30% to 70% would require an extra 270 theatre days (or £1.3m) yearly. The minimum number of operations required for training must be defined and the proportion of supervised operations undertaken by trainees substantially increased. Service and financial implications will have to be addressed. Action is needed urgently, as the first trainees will become consultants in less than five years.

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BMJ 1997;314:891–5

Introduction

During the past decade many official reports reorganising the National Health Service have combined to reduce the level of general surgical training. *Achieving a Balance: Plan for Action* proposed an increase in the number of NHS consultants and a proportionate decrease in the number of trainees.[1] To a large extent its proposals have not been fulfilled. The confidential enquiry into perioperative deaths[2] recommended greater consultant participation in emergency surgery. The "new deal" for junior doctors' hours[3] and the introduction of specialist training[4] have reduced surgical training time by around two thirds.[5] There will be a further reduction in experience if "hard pressed" specialties are limited to 56 hours a week or if the European Commission imposes a limit of 48 hours a week. Other changes such as the increasing trend to day case surgery, waiting list initiatives, and the use of staff grade surgeons, nurses, and surgeon assistants will all remove ideal training cases from trainees.

In order to provide trainees with the necessary practical experience the intensity of surgical training

will have to be increased. The practical implications of providing this intensive training do not seem to have been fully considered. We conducted an objective assessment of whether current general surgical practice within a single health board can satisfactorily accommodate the requirements of the proposed shortened general surgical training programme.

Methods

The study was carried out in three stages.

Stage 1

A postal questionnaire was sent to every general surgical consultant (trainer), senior house officer, and specialist registrar (trainees) in the south east Scotland general surgical training scheme. Subjects included trainers and trainees in district general and teaching hospitals who were working in both general surgery and specialist units. They were presented with a range of general surgical operations (indicator operations) and asked to state the ideal number of supervised and unsupervised operations that trainees should be expected to undertake during three periods of surgical training (senior house officer and specialist registrar in years 1-3 and 4-6). The mean number of indicator operations considered ideal for training was calculated.

The distribution of trainees throughout Lothian before and after the introduction of the present training programme was obtained from the chairmen of the training schemes. In the present scheme there were 35 trainees (17 senior house officers, 18 specialist registrars), an overall increase of 25%. Previously there had been 28 trainees (12 senior house officers, seven registrars, nine senior registrars).

The total number of indicator operations required in Lothian to provide the ideal training was the product of the mean number of recommended training operations and the number of trainees. Because some general surgery in Lothian is undertaken only in specialist units it was assumed that trainees could receive training only appropriate to the unit in which they worked. For example, training in breast surgery was not expected in the vascular unit. Surgical trainees based in the transplant and intensive care units and three staff grade surgeons were excluded from the calculations.

Stage 2

General surgical activity within Lothian was obtained from the Lothian Surgical Audit database.[6] This provided the total number of general surgical operations, including indicator operations, actually undertaken in Lothian during 1994. This was compared against the ideal number of indicator operations recommended by the trainers and trainees and any difference calculated.

Stage 3

A prospective study of skin to skin operating times for five indicator operations was conducted at the Eastern General Hospital. As the aim was to compare skin to skin times for various combinations of trainees and trainers, the patients selected were simple cases with a similar degree of complexity. For example, recurrent operations and obese patients were excluded, as they would not normally be suitable for training. The total skin to skin time required to perform each timed indicator operation was then calculated for each combination of surgeons. The additional time required for training could then be estimated. This calculation could be repeated after changing the proportion of operations undertaken by trainees and whether or not the operations were supervised.

Using the Lothian Surgical Audit database we estimated the total skin to skin operating time (the product of the total number of operations and the mean recorded time) for these five timed indicator operations across the whole of Lothian. The five timed indicator operations represented 32% of the workload and 36% of the caseload for all general surgical operations in Lothian.[7] We therefore assumed that these timed indicator operations represented one third of the total general surgical activity across Lothian. The total skin to skin operating time for all general surgery across Lothian could then be estimated. This calculation could be repeated after adjusting the proportion of operations performed by trainees. Thus an estimate of the total number of additional days required for training could then be calculated (seven skin to skin hours being taken as representing one theatre day).

Table 1 Mean numbers of operations that trainers recommended that individual trainees should undertake each year

	Senior house officer			Specialist registrar: Years 1-3			Specialist registrar: Years 4-6			Total		
Operation	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
Breast biopsy	14	10	14	7	8	16	2	4	23	23	22	53
Haemorrhoidectomy	8	6	6	4	6	9	1	3	14	13	15	29
Inguinal hernia	17	12	7	8	7	19	2	3	21	27	22	47
Varicose veins	14	11	10	17	14	20	2	7	25	33	32	55
Mastectomy	17	4	1	10	6	6	5	7	9	32	17	16
Colonic resection	20	3	0	13	9	3	7	9	11	40	21	14
Gastrectomy for cancer	6	0	0	6	2	0	4	5	2	16	7	2
Laparoscopic cholecystectomy	21	6	0	14	13	6	7	10	18	42	29	24
Femoropopliteal bypass	13	0	0	12	6	0	6	9	9	31	15	9
Mastectomy + latissimus dorsi flap	6	0	0	9	2	0	6	6	3	21	8	3
Total colectomy and ileal reservoir	5	0	0	6	1	0	4	3	2	15	4	2
Oesophagogastrectomy	5	0	0	6	1	0	6	4	1	17	5	1
Abdominal aortic aneurysm	8	0	0	9	2	0	7	8	5	24	10	5

A = Trainee assisting consultant. B = Trainee operating with consultant assisting. C = Trainee operating alone or with more junior assistant.

Results

Questionnaires were sent to 52 trainers and 44 trainees; 27 (52%) and 15 (34%) respectively responded. The mean numbers of indicator operations recommended by the trainers and the trainees were very similar, so only data for trainers were used. Table 1 shows the mean numbers of indicator operations recommended by the trainers. Table 2 gives the actual numbers of indicator operations performed in Lothian. Table 2 also shows the differences between the numbers of operations required for training and the actual numbers performed.

Table 3 shows the mean skin to skin operating times for various combinations of trainer and trainee undertaking the five indicator operations. At this hospital each 10% increase in the proportion of operations undertaken by trainees would require an extra 23 theatre days a year. If the proportion of general surgi-

Table 2 Yearly numbers of operations estimated to provide adequate training at each stage and differences between total numbers of training operations required and actual numbers of operations undertaken each year

	Senior house officer			Specialist registrar						Total			Total required for training	Actual operations performed	Difference
				Years 1-3			Years 4-6								
Operation	A	B	C	A	B	C	A	B	C	A	B	C			
Breast biopsy	14	10	14	7	8	16	2	4	23	23	22	53	98	433	335
Haemorrhoidectomy	106	93	86	53	87	142	20	44	208	179	224	436	839	338	–501
Inguinal hernia	233	172	95	126	100	288	33	49	317	392	321	700	1414	1083	–331
Varicose veins	224	171	163	282	244	337	36	113	427	542	528	927	1997	1326	–671
Mastectomy	17	4	1	10	6	6	5	7	9	32	17	16	65	134	69
Colonic resection	277	36	0	193	130	45	100	138	169	570	304	214	1089	651	–438
Gastrectomy for cancer	74	1	0	77	24	2	52	54	20	203	79	22	304	40	–264
Laparoscopic cholecystectomy	296	77	0	210	198	96	110	155	267	616	430	363	1409	598	–811
Femoropopliteal bypass	27	0	0	25	11	1	13	17	17	65	28	18	113	88	–25
Mastectomy + latissimus dorsi flap	6	0	0	9	2	0	6	6	3	21	8	3	31	23	–8
Total colectomy and ileal reservoir	50	0	0	63	12	0	45	37	19	158	49	19	226	48	–178
Oesophagogastrectomy	64	0	0	75	12	0	72	53	14	211	65	14	290	19	–271
Abdominal aortic aneurysm	17	0	0	18	4	0	13	16	9	48	20	9	78	132	54

A = Trainee assisting consultant. B = Trainee operating with consultant assisting. C = Trainee operating alone or with more junior assistant.

Table 3 Mean and range of operating times (minutes) for five indicator operations and various combinations and grades of surgeon and assistant. Registrar includes both experienced overseas trainee and previously appointed senior registrar

	Consultant and any trainee			Any trainee and consultant			Senior house officer and consultant			Registrar and any assistant			Registrar and consultant		
Operation	No	Mean	Range	No	Mean	Range	No	Mean	Range	No	Mean	Range	No	Mean	Range
Varicose veins	8	30	23-46	19	44	26-80	17	42	26-80	14	39	23-80			
Haemorrhoidectomy	7	18	8-26	10	27	13-48	6	25	13-45	10	27	13-48			
Inguinal hernia	10	27	16-40	14	48	18-70	13	48	31-70	19	38	15-58			
Right hemicolectomy	2		63,90	6	110	80-178	4	125	85-178	5	100	80-120			
Laparoscopic cholecystectomy	6	51	30-75	17	86	35-139	9	93	70-110	17	75	35-139	8	79	35-139

cal operations undertaken by trainees in Lothian was increased from one in three to two in three an extra 270 theatre days a year would be required.

Discussion

This study suggests that Lothian hospitals (serving a population of around 750 000) will not be able to provide the level of general surgical training that trainers and trainees believe is required. So far as we know this is the first objective study assessing the implications of the recent changes to surgical training across a region. Indeed, it is unlikely that a similar study could be undertaken elsewhere in the United Kingdom because the Lothian Surgical Audit database is a unique regional record of surgical activity.[6 8] However, there is no reason to think that the training opportunities in other health boards or surgical specialties will be any different.

The numbers of training operations proposed for individual trainees were not unrealistic. Many people might consider them a conservative estimate. However, the larger number of trainees and the shorter training period meant that the total number of training operations required across the region greatly exceeded the number available. Laparoscopic cholecystectomy can be used as an example. During the first year of surgical training a senior house officer would perform six of these operations under supervision and none independently. During each of the first three years a specialty registrar would perform a further 13 under supervision and six independently. In each of the second three years these figures would be 10 and 18 respectively.

Despite these very modest individual requirements the regional need as assessed by the trainers was for 1409 laparoscopic cholecystectomies. However, only 598 were actually undertaken, a shortfall of 811. These figures assume that 60% of laparoscopic cholecystectomies are undertaken by trainees. The reality is that in 1995 only 30% were performed by trainees. Even if consultants and staff grade surgeons did not perform a single laparoscopic cholecystectomy there would still be a 50% shortfall in the number required for training. If the proportion of laparoscopic cholecystectomies undertaken by trainees was increased from 30% to 70% an additional 92 theatre days would be required in Lothian. This does not include the extra time required for anaesthetic training or setting up the theatre.

Loss of training opportunities

The true situation is almost certainly substantially worse. In future senior house officers will undertake only six months and not 12 months of general surgery, and as this will be their first surgical experience they are likely to undertake proportionately fewer cases than in the full year assumed for this study. The questionnaire also assumed that trainees would receive training in each operation every year. This will not be so. Trainees will have to rotate through units that offer little or no experience in some types of surgery. These calculations also assume that every operation is suitable for training, which will not be the case. Realistically, trainees might be expected to receive 50-70% of the training assumed in this study.

More difficult to assess is the loss of training opportunities that have undoubtedly occurred from more subtle changes in surgical practice. For example,

attachments will be for shorter periods and training opportunities will be lost at each rotation while the consultant assesses the new trainee.[9 10] Increasing calls for senior staff to be responsible for day cases and waiting list initiatives will deny trainees access to ideal training operations. The increasing use of staff grade surgeons, theatre assistants, and nurses will further deprive trainees of cases that are typically ideal for training. In future, contracts should insist that a minimum proportion of day case and waiting list operations are undertaken by both supervised and unsupervised trainees.

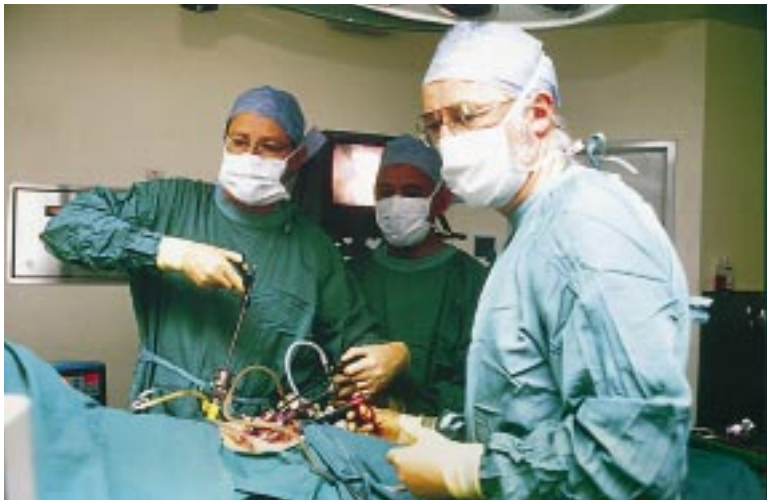
Senior surgical registrars in the United Kingdom were traditionally appointed as fully trained "stand alone" consultants. As matters stand now the first of the present specialty registrars will be expected to discharge the same responsibilities when they become consultants in less than five years. There is no doubt specialty registrars will have neither the depth nor breadth of experience that their predecessors had. It is essential that all concerned recognise that this potential problem will become a real problem in less than five years.

Possible solutions

A return to the past, when trainees were stated to have been overexperienced but undertrained,[11] would not be appropriate or acceptable to trainees, politicians, or patients. No single solution will solve this problem but the following possibilities should be considered.

- Purchasers, providers, and educational authorities must agree that teaching and training are in every way of equivalent value to clinical work. Until there is this commitment training will always be subjugated to service requirements.
- This means that the number and proportion of both supervised and unsupervised operations undertaken by trainees will have to be substantially increased. This would require absolute numbers to be defined and included in the contracting process. This is implied in the Department of Health guide to specialist registrar training, which states that assessment should "measure progress against defined criteria" and that trainees "have to meet an agreed standard."[12] However, to date neither the Royal Colleges of Surgeons nor the postgraduate deans have been prepared to define these criteria. As a result consultants are trapped between managers who wish to see service activity increased and training bodies that wish to see training increased. In large part these objectives are incompatible and consultants will become the pawn in the middle. This can only contribute further to consultant disillusionment.
- To accept that trainees will not receive enough training before becoming consultants and will complete their training after taking up their consultant appointment. In the early years a junior consultant may frequently require assistance from senior colleagues. This has obvious service implications.
- A natural extension of this concept would be to plan the introduction of a subconsultant grade. This has not previously been considered an attractive option by the surgical community but would seem to be the inevitable consequence of the current arrangements.
- To provide additional funding to selected trainees, who would then undertake "specialist fellowships" and assume responsibility for major and complex cases.
- To recognise that narrow specialisation is the way of the future and to rotate trainees only to those units which offer the relevant training in their chosen specialty. This would have important future logistical implications for many district general hospitals.
- To accept that the recent 60% reduction in trainees' overall training is excessive. Two options would be to increase the basic surgical training period by an additional year of general surgery and to permit a limited increase in the number of hours on call.
- For trainers and educational authorities to agree that the immediate priority is to preserve and increase training. Managers and politicians should be left to sort out the inevitable growth in waiting lists.

The government's stated aim is to increase the number of consultants[1] but thus far expansion has been limited. Failure to increase the number of consultants lies at the heart of the present problem. However, additional consultants are an expensive investment and many trusts will not create new posts without increased funding. At present there are unfilled consultant vacancies because of an acute shortage of trainees and so expansion is not possible. This is unlikely to be resolved before the first of the current (undertrained) specialist registrars become consultants.



ANTONIA REEVE

Fig 1 Consultant assisting at laparoscopic cholecystectomy

Additional operating time for trainees

Though it is self evident that trainees require more time than consultants to perform operations, no previous report has studied the additional requirements in detail. One retrospective study reviewed overall activity for a mixture of cases but did not undertake a detailed analysis of specific training operations.[13] In that study it was possible to determine whether the trainee was the surgeon but not whether he or she was supervised. In this study trainees required 50-75% more time than the consultants to undertake simple operations. This may be an optimistic assessment because by current standards all the trainees were comparatively experienced. The three senior house officers in this study were at the end of their first year whereas future senior house officers will be in post for only six months. One specialist registrar in this study was an experienced

overseas registrar and the other an experienced senior registrar converted from a career grade registrar post.

Notably, only the specialist vascular and breast units could provide the trainees with the required number of operations. This was partly because the operations were more concentrated but also because the ratio of trainees to trainers was typically one to one whereas it was nearer one to two in the other units.

At an average theatre expenditure of £700 an hour the extra 270 days required would cost Lothian Health an extra £1.3m for general surgery alone. There is no reason to believe that the situation in other surgical specialties will be substantially different. Hence the increased cost of surgical training to Lothian Health will be considerable. An independent study has estimated the increased cost of the specialist training proposals as 6% of trust income.[14]

In conclusion, this study has shown that the present proposals for general surgical training will not provide trainees with enough experience. This problem needs to be addressed urgently, as the first specialist registrars will become consultants in less than five years.

We thank the Royal College of Surgeons of Edinburgh and Lothian Surgical Audit for their help.

Conflict of interest: None.

Funding: None.

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(Accepted 31 December 1996)

Primary care—opportunities and threats

The changing meaning of the GP contract

Jane Lewis

Summary

The meaning of the GP contract has changed since the last major upheaval in the mid-1960s. The government has always dealt with general practitioners as independent contractors, but the way in which it treated them in 1990 was entirely different from the way in which they were treated in 1966. In 1966, the profession's independent contractor status effectively served to protect professional autonomy. In 1990, with the change in the form of government towards a "contract state," general practitioners were treated as independent contractors more in the sense of business entrepreneurs. The article finishes by raising the issue of how general practitioners can gain control over the medicopolitical agenda in the future.

General practitioners were extremely hostile to the contract that was imposed on them in 1990. Yet the profession had signed up to many of its provisions. In 1985 Michael Wilson, the then chairman of the General Medical Services Council, wrote to the minister of health, Barney Hayhoe, with proposals for extending the range of services offered by general practitioners to include the extension of cervical cytology screening, a comprehensive scheme for paediatric surveillance, and minor surgery—all specific proposals that were taken up by the government in 1990. Nor were many of the worst fears of general practitioners about the workings of the contract realised. Pay increased (though the increased delivery of items of service was deemed by the government to have resulted in "overpayment") the cash limits on reimbursement for expenses proved initially generous; and the increased weight accorded capitation payments did not result in an increase in list size, although it served to thwart general practitioners' longstanding desire for a reduction. Why, then, was the hostility so great?

The answer lies in the changing meaning of contract. Since the introduction of national health insurance in 1911, the government had dealt with general practitioners as independent contractors, but the way in which it treated them in 1990 was entirely different. The contrast with the dispute in the mid-1960s is particularly strong. In the 1960s the political culture emphasised planning, corporatism, and expertise; by the end of the 1980s it emphasised the importance of markets and consumers. In the late 1980s there was a paradigm shift in the way in which public services of all kinds—housing, education, and community care, as well as health—were delivered.[1] Market principles were introduced into the public sector and contract became the vehicle for achieving the goals of increased efficiency, choice, quality, and accountability. The move towards what some social sci-

This is the final article in a series discussing the imminent reforms in primary care

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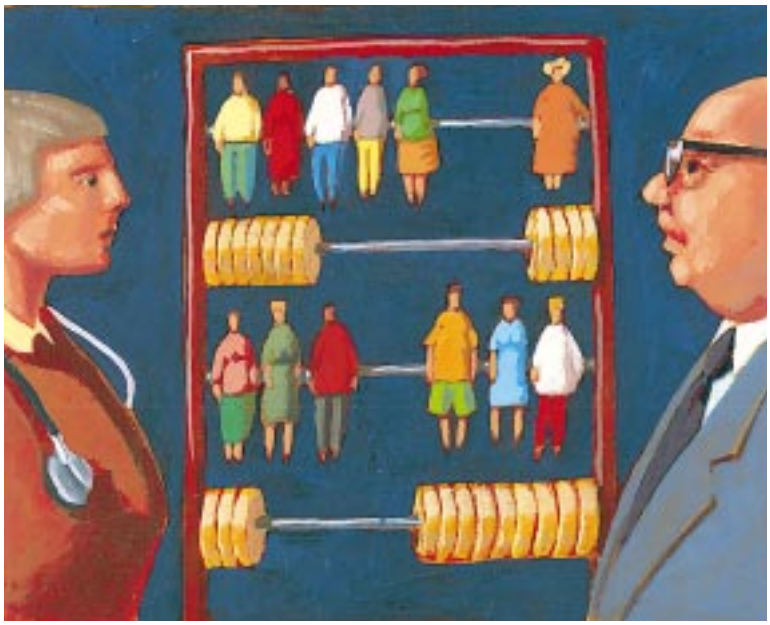
BMJ 1997;314:895–8



ALAISTAIR TAYLOR/THE INKSHED

entists have called the contract state,[2] in which hierarchies and professional values have been replaced by "quasi-markets" [3] and managerial values, has in turn had major implications for the way in which general practitioners have been treated as contractors.

The mid-1960s

In 1966, general practitioners got what they asked for after considerable struggle. The postwar system of remuneration had worked on the basis of a rather rigid and unfair "pool" which, among other things, calculated capitation payments on the basis of the number of doctors rather than patients and which failed to reimburse doctors directly for their expenses. General practitioners successfully demanded a new system of payment, one based on a more mixed system that included capitation payments calculated on the basis of the number of patients, a basic practice allowance, and fees for service. There was as little support for a wholly salaried system as there had been in the 1940s. The famous "charter," which formed the basis for negotiations in 1965, represented a shrewd strategic move on the part of the GMSC. The four principles of the charter were the right to practise good medicine in up to date, well staffed accommodation; the right to practise medicine with the least possible intrusion by the state; the right to enjoy proper payment for the services rendered; and the right to financial security. The demand for the means to deliver a good service was thus put before pay, and BMA Council members emphasised that the charter was as much a patients' as a doctors' charter. As Dr Ronald Gibson, chairman of the Representative Body, put it: "Our approach must be towards more money for the service and not, in the first place, for ourselves." [4] This contrasts with 1990, when the language of consumerism was captured by the government, leaving the profession disadvantaged.

General practitioners asked for the means to be given to enable them to do a good job and to be left alone to do it. As one doctor wrote in the *BMJ* at the beginning of 1965: "We want to be trusted individually and as a profession, and we want to play the game without a surfeit of regulations, orders, and officials." [5] In large measure, this was what general practitioners achieved in 1966. However, this does not mean that the government had no concerns about what actually went on in general practice. A Ministry of Health memorandum filed with the document of the Fraser working party (set up by the BMA and the Department of Health in 1964 to investigate the terms and conditions of general practice) noted that previous reports on general practice had all "refrained from saying anything that would imply that some doctors were bad." [6] It was not quite that it was assumed in the 1960s that all doctors were good, as Margot Jefferys and Hettie Sachs have suggested.[7] The government certainly had doubts about the quality of general practice, but it chose not to do anything about them and to trust the profession to use the provisions of the 1966 contract to put its house in order.

Thus the negotiations of the mid-1960s respected the professionalism of general practitioners and avoided profound underlying issues to do with the nature and content of general practice. However, the issue of quality did not go away and was highlighted in the evidence given by the Royal College of General Practitioners to the Royal Commission on the NHS in 1977 and in a series of reports published by the college in the 1980s, beginning with *What Sort of Doctor*, published in 1985.[8] Quality came to the forefront when the government seized the initiative in 1990, expressing impatience with the notion of professional altruism and determined to use market principles to pursue a consumerist agenda.

Proposals for reform in the 1980s and the 1990 contract

At the core of the 1986 green paper on primary care was a concern about cost and quality. The document advocated the introduction of a good practice allowance, citing the Royal College of General Practitioners' 1985 report on quality.[8] However, despite support from leaders within the Royal College, the profession opposed the allowance. The GMSC argued that any payment in recognition of quality had to be achievable by all general practitioners. The proposed allowance would be achievable only by some and would therefore serve only to widen the gap between good and bad practitioners.[9] In addition, as Peter Toon has pointed out, there was no consensus among general practitioners as to what constituted good practice.[10] The government gave up on the idea of a good practice allowance but, as the language of the 1987 white paper on primary health care showed, it had no intention of abandoning its aim to make services more responsive to the needs of the consumer and to raise the standards of care. In many respects the 1990 contract served as the vehicle for making doctors more accountable for what they did.

In 1990 the gentleman's agreement between general practitioners and the government ceased.[11] It was not inappropriate for the government to specify more closely what it wanted to buy from a group of people who prided themselves on their status as independent contractors. However, general practitioners had historically used their independent contractor status as a means to defend their professional autonomy.

Now the government seemed to be trampling on this and to be using its statutory muscle to impose clinical direction for which there was little or no evidence regarding effectiveness—for example, in respect of health checks for elderly patients and those who had not seen a general practitioner for three years.[12] Perhaps the most despised imposition was that of health promotion clinics, with payments for "patients in packs of 10," notwithstanding the potential for financial gain. In 1990, the government treated general practitioners as self interested individuals who would respond rationally to economic incentives. This was not an unreasonable expectation to make about people who prided themselves on being independent contractors. However, there was no evidence to suggest that general practitioners would behave as self interested entrepreneurs. For example, Krasnik *et al*'s study of remuneration systems showed that general practitioners were more inclined to seek to fulfil a target income rather than to maximise income, as the model of the self interested professional would have predicted.[13] As Rosen put it, while doctors' behaviour is determined in part by payment, it would be wrong to regard professionals as "businessmen without licences." [14]

The new meaning of contract and GPs' independent contractor status

Major changes in the contract were proposed in the 1996 white paper, *Choice and Opportunity*: a salaried option for general practitioners, either within partnerships or with other bodies; practice based contracts; and a single budget for general medical services, other hospital and community health services, and prescribing.[15] These changes are the logical response to the development of the internal market in health care, which has taken on a life of its own, with very rapid changes in the configuration of purchasing and providing, particularly in respect of general practitioner fundholding and commissioning.

As the purchaser-provider split has created both greater centralised control and more fragmented provision, so general practitioners' nationally negotiated contract has come to seem more anomalous. Paradoxically, the operation of the quasi-market has also brought the issue of a salaried service back on to the agenda. There was very little discussion of salary between 1966 and the 1990, when the NHS quasi-market raised the possibility of services being commissioned from practices rather than from individual general practitioners. As the white paper suggests, it is also the case that many general practitioners do not want to make the personal investment and long term commitment required by a partnership and would also welcome more regular hours and the possibility of reconciling work and family responsibilities.

Thus the changed meaning of contract has very quickly served to put a large question mark over aspects of general practitioners' status as independent contractors, which has historically been viewed as the chief means of securing professional autonomy. The changes to the GP contract in the context of the rapidly developing internal market mean that general practitioners must grapple more explicitly with what it is that they do and how far they can exercise control over it. In the 1990s, the profession has realised the importance of regaining the initiative. While they were successful in this respect in the mid-1960s, their role in 1989-90 was largely reactive.

The GMSC's responses

The GMSC has focused on discussing how to define the core of general practice and the extent to which negotiations should be local rather than national. In 1991 it undertook a large survey of general practitioners which achieved a 70% response rate and which served as the basis for the GMSC's renegotiation of the most vexing parts of the 1990s contract and for the development of the council's "core services" strategy. In *Building Your Own Future* the council told general practitioners that their "unreal" perception of the negotiating process (in terms of underestimating the government's opposition to "collectivism") was matched "by a lack of understanding of the nature of the contracts of NHS GPs" and by "excessive confidence in the justness of the profession's position."[16] The following year the new chairman of the GMSC, Ian Bogle, told general practitioners that the profession's stance on quality was crucial and that if they wished to stop excessive monitoring by the family health service authorities they should opt for quality assurance and a system of accreditation.[17] And in 1996 the council highlighted the question of defining the core in a discussion paper with an interesting subtitle: *Defining Core Services in General Practice—Reclaiming Professional Control*.[18]

The RCGP's responses

In its 1995 report on the nature of general practice the Royal College of General Practitioners, which lost many members after the imposition of the 1990 contract, drew a stark picture of professional versus contractual requirements, emphasising the negative implications of the latter, notwithstanding its own record in exposing the inadequacies of the profession in regulating quality.[19] The college pointed out that independent contractor status allowed each general practitioner some degree of autonomy in determining the balance of the "practice culture" between population centred and person centred medicine. The first threat to this autonomy was posed by the way in which the new contract began to define the core services that the general practitioner had to provide. The second threat came from the rapid development of general practitioner commissioning, which tipped the balance against the practice of person centred medicine.

General practitioners who emphasised the importance of the quality of the individual consultation—in the humanist tradition of Balint—were not favourably disposed to the population centred performance indicators of the new contract culture. Certainly, the government's 1996 proposals for practice based contracts and some salaried service threaten to erode professional autonomy further. The practice of some general practitioners will be dictated by others or by trusts. General practitioners will no longer be such a unitary body, which poses difficulties for the profession's leaders, although some general practitioners may be content to trade professional

autonomy and power for a greater degree of (salaried) comfort.

Differences in the autonomy exercised by general practitioners would also have implications for their status in relation to other members of the primary health team; the Royal College of General Practitioners' 1995 document made a strong case for putting the general practitioner at the centre of the "core primary care team," as someone with a unique clinical role as a diagnostician. However, by offering general practitioners the possibility of engaging in "total purchasing" by legitimating a unitary budget, the Primary Care Bill may also offer practices greater control and autonomy.

The future

General practitioners should be in a strong position given the government's increasingly explicit commitment to the development of primary care, although making primary care the cornerstone of the NHS "presupposes a degree of strategic incorporation which stands in stark contrast with the semi-detached status it has occupied historically." [20] The issue of defining core general medical services has become more urgent with the advent of the Primary Care Bill. General practitioners remaining in traditional practice and also those who may form experimental schemes to merge hospital and general medical services funding streams need to know the limits of their general medical services responsibilities.

After what was perceived by most general practitioners as the defeat of 1990, the profession's leaders have shown a willingness to work within the new boundaries. General practitioners stand a better chance than many other groups of professionals of exercising influence and control over the main tools of the new managerialism, chief among which are the measures associated with quality control. Recent research on general practitioner fundholding has highlighted the extent to which general practitioners have become much more involved in local health planning in the 1990s.[21]

The history of general practice in the late 20th century shows the difficulty that leaders, particularly in the Royal College, have had in persuading general practitioners of the necessity for action in this respect. Historically there have always been general practitioners who were prepared to seize the initiative—for example, in improving their practices after 1966—and those who were not. The circumstances of the mid-1990s open the way for greater divisions between general practitioners. Furthermore, despite the discussions set in train by the Royal College of General Practitioners and the General Medical Services Council, the government remains firmly in the driving seat in 1996, albeit after much more consultation in the form of the "listening process" than marked the beginning of the decade. In the future, much will depend on how far the profession succeeds in setting the agenda. However, the government's commitment to securing greater accountability is unlikely to go away.

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(Accepted 17 February 1997)

ONE HUNDRED YEARS AGO

Chewing gum

The question has been raised whether there is any reason for supposing that the practice of gum chewing, so prevalent in the United States, is on the increase in this country. We have made some inquiries, and have ascertained that many young women—students, actresses, and others—appear to have acquired this disgusting habit, and are inveterate chewers. We have examined specimens of chewing gum obtained from various fashionable sweet shops in London, and find that, as a rule, it consists of rubber, flavoured with aniseed or peppermint, or some other aromatic substance. Some kinds are made with resin, and some are advertised as containing pepsin, or as being peptonised. They are all absolutely insoluble, and if constantly chewed produce an increased flow of saliva, which is either expectorated or swallowed. A few days ago an inquest was held at Lincoln on a child 8 years of age, who died from the effects of eating a pellet of the substance. The symptoms preceding death were those of gastritis, and at the post-mortem examination it was found that the mucous membrane of the stomach was inflamed, and that there was much peritonitis. The coroner pointed out that the distribution of such dangerous stuff to young children was a very improper proceeding, and the jury fully endorsing his remarks, added that in their opinion its sale should be absolutely prohibited. The danger seems to us to be in the fact that children who buy sweets are often too young to read, and cannot be made to understand that something bought at a sweetstuff shop, and having all the appearance of a candy, is "not to be eaten." A bolus of resin or of india rubber, coloured perhaps with aniline dye, would remain undissolved in the stomach, and would undoubtedly act as an irritant. (*BMJ* 1897;ii:1112.)