possible early retrograde messenger. *Proc Natl Acad Sci USA* 1991; **88**:11285-9.
11 Bagetta G, Iannone M, Del Duca C, Nistico G. Inhibition by N^{ω}-nitro-L-arginine methyl ester of the electrocortical arousal response in rats. *Br J Pharmacol* 1993;**108**:858-60.
12 Moore PK, Babbedge RC, Wallace P, Gaffen ZA, Hart SL. 7-Nitro indazole, an inhibitor of nitric oxide synthase, exhibits anti-nociceptive activity in the mouse without increasing blood pressure. *Br J Pharmacol* 1993;**108**: 296-7.
13 Liew FY, Li Y, Severn A, Millot S, Schmidt J, Salter M, *et al.* A possible novel pathway of regulation by murine T helper type-2 cells (T_h2) of a T_h1 cell activity via the modulation of the induction of nitric oxide synthase in macrophages. *Eur J Immunol* **21**:2489-94.
14 Vallance P, Moncada S. Role of endogenous nitric oxide in septic shock. *New Horizons* 1993;**1**:77-87.
15 Conrad KP, Josse GM, Kruszyna H, Kruszyna R, Rochelle LG, Smith RP, *et al.* Identification of increased nitric oxide bio-synthesis during pregnancy in rats. *FASEB J* 1993;7:566-71.
16 Kurtzman J, Natuzzi ES, Buscher CA, Harrison M, Ursell P, Heymann M, *et al.* Human preterm labor is associated with decreased nitric oxide synthase activity. *Endothelium* 1993; **1**(suppl):S75.
17 Barbul A. Arginine: biochemistry, physiology and therapeutic implications. *Journal of Parenteral and Enteral Nutrition* 1986;**10**227-38.
18 Snyder SH. Janus faces of nitric oxide. *Nature* 1993;**364**:577.
19 Middleton ST, Shjorthouse M, Hunter JO. Increased nitric oxide synthesis in ulcerative colitis. *Lancet* 1993;**341**:465-6.
20 Boughton-Smith N, Evans SM, Hawkey CJ, Cole AT, Balsitis M, Whittle BJR, *et al.* Nitric oxide synthase activity in ulcerative colitis and Crohn's disease. *Lancet* 1993;**342**:338-40.
21 De Belder AJ, Radomski MW, Why HJF, Richardson PJ, Bucknall CA, Salas E, *et al.* Nitric oxide synthase activity in human myocardium. *Lancet* 1993;**341**:84-5.
22 Petros A, Bennett D, Vallance P. Effect of nitric oxide synthase inhibitors on hypotension in patients with septic shock. *Lancet* 1991;**338**:1557-8.
23 Vallance P, Leone A, Calver A, Collier J, Moncada S. Accumulation of an endogenous inhibitor of nitric oxide synthesis in chronic renal failure. *Lancet* 1992;**339**:572-5.
24 Feelisch M. The biochemical pathways of nitric oxide formation from nitrovasodilators: appropriate choice of exogenous NO donors and aspects of preparation and handling of aqueous NO solutions. *J Cardiovasc Pharmacol* 1991;**17**(suppl 3):S25-33.
25 Riegel F.Diseases of the trachea and bronchi. In: Ziemssen HV, ed. *Cyclopaedia of the practice of medicine.* Vol 4. London: Sampson, Low, Martson, Saerle and Rivington, 1876:275-586.
26 Rossaint R, Falke KJ, Lopez F, Slama K, Pison U, Zapol WM. Inhaled nitric oxide for the adult respiratory distress syndrome. *N Engl J Med* 1993;**328**: 399-405.
27 De Belder AJ, MacAllister R, Radomski MW, Moncada S, Vallance P. Effects of S-nitroso-glutathione in the human forearm circulation. Evidence for selective inhibition of platelet activation. *Cardiovasc Res* 1994;**28**:591-4.
28 Drexler H, Zeiher AM, Meinzer K, Just H. Correction of endothelial dysfunction in coronary microcirculation of hypercholesterolaemic patients by L-arginine. *Lancet* 1991;**338**:1546-50.
29 Moore PK, Wallace P, Gaffen Z, Hart SL, Babbedge RC. Characterization of the novel nitric oxide synthase inhibitor 7-nitro indazole and related indazoles: antinociceptive and cardiovascular actions. *Br J Pharmacol,* 1993;**110**:219-24.
30 Gross SS, Levi R. Tetrahydrobiopterin synthesis: an absolute requirement for cytokine-induced nitric oxide generation by vascular smooth muscle. *J Biol Chem* 1992;**267**:25722-9.

Conducting clinical research in the new NHS: the model of cancer

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The United Kingdom Coordinating Committee on Cancer Research represents the major organisations funding cancer research in the United Kingdom. The deliberations of a working party convened by the committee to evaluate recently expressed concerns that the changes in the NHS threaten research, especially clinical trials to evaluate new treatments, are reported. A survey of contributors to trials coordinated by the committee showed that half are now experiencing difficulties in continuing to participate in clinical trials. The two major problems identified were lack of time and of staff, especially for NHS staff in non-teaching hospitals. Recent changes in junior doctors' hours and proposed reductions in the length of time for training will exacerbate this. It is possible to identify the direct and indirect excess costs of conducting research in the NHS, but currently the mechanism does not exist to designate funds specifically for this purpose. Consultation with the regional directors of research and development confirmed that the service increment for teaching and research is not the solution for this. Proposals are made to secure future clinical research in the NHS, including finance, indemnity, the licensing of new drugs, the greater use of nurse counsellors, and the value of cancer registries.

Introduction

The United Kingdom Coordinating Committee on Cancer Research is an independent body representing the major organisations funding cancer research in the United Kingdom. Clinical cancer research can cover many aspects of malignant diseases, and it is important to distinguish research involving NHS organisational and managerial issues from those dealing with the evaluation of (new) treatments. It is the latter that is of particular concern to the committee. We seek to encourage, promote, and facilitate cancer research, particularly through the medium of randomised clinical trials. This has never been easy, and the changes now being introduced in the NHS are further exacerbating the difficulties of conducting clinical research. We examined some of the issues involved and have made proposals for improvement.

Cancer is a major health problem in the United Kingdom and was responsible for 163 940 deaths in 1991. As the population lives longer cancer is likely to become a greater burden to the NHS. Despite improvements in techniques and equipment in surgery and radiotherapy, better imaging and staging, and the development of new cytotoxic drugs, it remains the case that most cancer patients die of cancer. There is, therefore, a compelling need to improve treatment by the introduction of new regimens, new combinations, or better scheduling of existing treatments.

It is now widely recognised that the most accurate and effective way of evaluating treatments is a randomised controlled trial. Randomisation avoids bias in the selection of patients, and analysing results on an intention to treat basis ensures that treatments are tested in a way that reflects the realities of clinical practice. Also, effective assessment of new therapeutic strategies is essential to avoid the inappropriate use of scarce resources. There remains, however, a lack of understanding by many of the clinical community and NHS management about the need for clinical trials and the methods entailed. There is still a widely held view that decisions about which treatment is better can be based on clinical experience rather than randomised comparisons.

To identify small or moderate differences in outcome requires large numbers of patients. Even before the introduction of the current changes in the NHS it was a struggle to recruit adequate numbers of patients for clinical trials. Most clinicians are already hard pressed, and few with NHS contracts have any sessions available for research. For the most common solid tumours less than 5% of patients have the benefit of being entered into clinical trials. If this number declines further the impact of such trials on routine NHS practice and the academic skill which currently exists in the United Kingdom will be lost.

The Department of Health itself has recently drawn attention to the need to evaluate new treatments properly before they are introduced on a wide scale into

routine practice.[1] Some clinicians and an increasing number of patients recognise the importance of adequately testing new developments before they are widely used, to protect future patients from unnecessary morbidity, and to avoid unrealistic expectations from treatments. These confluent opinions should therefore lead to an increasing emphasis on clinical research, but the changes to the NHS threaten this. There is already evidence from several sources that continuing to participate in trials is becoming increasingly difficult.

Are trials being supported in the new NHS?

There is little doubt that service increment for teaching and research, no matter how attractive in theory, currently does not work in practice. The committee's secretariat wrote to the English regional directors of research and development asking them to explain how they allocated service increments and how they planned to support clinical trials. We are grateful that the replies were so frank. They were not, however, reassuring. It was encouraging that there was clearly a wish to support good clinical research, including clinical trials. How this is to be achieved is as much a cause for concern to the regional directors as it is to the committee.

Several replies pointed out that the service increment for teaching and research is not intended to cover project costs—that is, the excess service costs—but is meant to reimburse (or compensate) hospitals for the additional infrastructure needed to allow them to carry out research. This then begs the question how will the excess service costs be met? It was clear from the replies that there is currently no suitable mechanism for supporting large scale clinical trials. Indeed, one director wrote, "You ask how we are going to support clinical trials, and my answer is 'I only wish I knew.'" Another director explained that in his region the 25% allocated for research "is based on a mixture of grants and papers published. No part of this is specifically allocated to clinical trials."

Several directors drew attention to the task force convened by Professor Peckham that has been asked to establish the nature and extent of any problems with regard to the conduct of research and development in the NHS. Its terms of reference point out that any alternative mechanisms proposed must recognise that any new system will have to operate within available resources. Yet it is perfectly clear from the replies to the committee from the regional directors of research and development that the allocation of funds supporting clinical research is nowhere near big enough to support all nationally approved trials.

The current emphasis on market forces discourages participation in trials in which any associated costs are not met by the trial organisers. (Such costs may not necessarily be increased because in comparing two treatments the test treatment might be cheaper.) In practice, this encourages trials sponsored by the pharmaceutical industry. These are designed to gain a product licence or to show that a new compound has some effect on tumours; they are performed to benefit the company rather than to compare two treatments with the sole intention of improving the provision of health care. And while clinicians are directing their efforts to trials run by industry they will have little, if any, time or incentive for large scale trials of national importance.

The financial imperative from a market based NHS to avoid the "unnecessary" expense in undertaking a trial is the basis of real conflict. If, for example, clinicians really are uncertain about which of two treatments is best, why not settle for the cheaper? But the NHS has a commitment to improve treatment. This requires a commitment to undertake and complete trials, accepting that such a strategy carries financial implications. Unfortunately, this requirement is seldom recognised by purchasers of health care. It is assumed that trials are expensive. If one considers the overall costs of providing cancer care, however, the cost of a programme of clinical trials is minor in comparison. Furthermore, these costs should be weighed against the costs of using treatments that have not properly been evaluated and which may be suboptimal or inappropriate.

In 1990 the Department of Health commissioned the Alberman report on cancer registration and as a result set up a standing subcommittee on cancer registration. This indication of the importance given to cancer registration by the department has been welcomed, but there is still much room for improvement in the coverage and detail of registry data. The importance of registries in supporting both clinical trials and epidemiological studies is well recognised. There is a strong need for accurate national information on tumour site, stage, treatment, and outcome. It is essential that registries improve the quality of their data; increased resources might be needed to accomplish this.

A problem now being encountered that is a direct result of the new purchaser-provider agreements is that patients are being treated in local hospitals rather than being referred to specialist centres. In recent years several studies have shown that there is a survival advantage if treatment is given in a specialist centre, and this advantage will be lost if contracts are increasingly given to local hospitals that lack specialist cancer services. Also, as it is generally the specialist centres which enter patients into trials a decrease in referrals to cancer centres means that there is a reduced pool of patients being invited to participate. If the trend towards referring patients locally is to be continued, the Department of Health must ensure that the mechanisms are available for patients in district general hospitals to be entered into nationally agreed protocols.

A further problem that is directly related to the introduction of trusts is the question of how indemnity is provided for volunteers in trials. The current arrangements for indemnity are unsatisfactory now that the advantages of crown immunity have been lost as a consequence of devolution of responsibility for indemnity to individual provider units. Trusts now have to take the responsibility for providing indemnity yet are not funded to do so. To take out insurance to cover the potential payments will increase the costs of their services, which will be a disincentive in an environment driven by market forces. The Department of Health and the Association of the British Pharmaceutical Industry have drawn up guidelines for trials sponsored by industry, but most large phase III trials are not funded by industry. Several hospitals and local research ethics committees have refused approval for trials because of the lack of formal indemnity.

These problems have led to a worrying decrease in participation in clinical trials even among many previously ardent trialists. Add to these the difficulties of obtaining ethics committee approval because of the confusion that has arisen in the new NHS about indemnity and approval from hospital managers because of the cost implications and the problems of finding time to talk to patients to explain about the trial and it is little wonder that there is now an air of apathy, with clinicians being disinclined to invest the substantial effort needed to initiate and sustain trials.

Survey of trial participants

The coordinating committee has several treatment trials in progress throughout the United Kingdom on

several cancer sites. The first of these has been running for almost six years and has now been closed for entry, having recruited about one third of all eligible patients in the United Kingdom. The largest trial is called AXIS (adjuvant *x* ray and infusion study), looking at treatment of colorectal cancer, which has recruited over 2000 patients in four years. All clinicians participating in our treatment trials were sent a questionnaire and asked to identify which trials they participated in and to state whether they had encountered problems. If they had encountered problems, they were asked to elucidate the basis of these problems.

Of the 287 returns received, over half of the respondents said that they were finding it difficult to take part in these trials (table I). The main difficulty encountered was the lack of time to participate in clinical trials (table II). Many respondents identified the increased emphasis on audit and the need to attend administrative and managerial committees as time consuming, resulting in less time for research. The recent changes in junior doctors' hours and the anticipated reduction in the length of time in training will exacerbate this shortage of time considerably.

TABLE I—*Whether problems were experienced by 287 clinicians participating in clinical treatment trials organised by UKCCCR,* by region or country*

Region or country	Problems experienced	No problems experienced
Northern Ireland	4	2
East Anglia	5	3
North East Thames	11	15
North West Thames	5	6
South East Thames	8	7
South West Thames	6	6
Mersey	4	7
Northern	7	11
North Western	9	6
Oxfordshire	6	6
South West	8	5
Trent	14	9
West Midlands	12	8
Wessex	11	11
Yorkshire	8	8
Scotland	16	23
Wales	8	5
Republic of Ireland	3	1
Special Health Authority	2	1
Total	147	140

*United Kingdom Coordinating Committee on Cancer Research.

TABLE II—*Main problems (up to three) experienced by 147 clinicians participating in clinical trials organised by UKCCCR**

Type of problem	No of clinicians with problem
Administrative difficulties before achieving randomisation	36
Difficulty in gaining informed consent of patients or in providing counselling	66
Difficulty in collecting data or in following up patients	73
Lack of staff	81
Lack of funds	44
Lack of time	109
Other	20

*United Kingdom Coordinating Committee on Cancer Research.

Perhaps even more worrying is that the introduction of time limited contracts for consultants may mean that they are not willing to risk appearing less efficient than colleagues by spending time on entering patients into trials as this will reduce their "productivity." A theme throughout many of the responses was the need for dedicated research staff—nurses, data managers, or clerical staff—to relieve the doctors of much of the administrative workload associated with participating in trials.

Another disincentive identified by many participants is the difficulty encountered in obtaining approval from the local research ethics committee. The lack of a standard form means that some clinicians have to fill out three or four different forms, possibly attend the same number of meetings, then enter into correspondence to answer any queries.

Components of conducting clinical trials

- Researching the literature
- Consulting colleagues
- Writing the protocol
- Taking the protocol to protocol review
- If collaborative groups are involved, attendance at meetings
- Submission to local research ethics committees
- Investigations to confirm eligibility of ptients and staging of their disease
- Time with patients to explain trial and randomisation and obtain informed consent
- Data recording at entry
- Treatment
- Follow up

What is the basis of the problems?

The process of conducting a clinical trial entails many components, each of which has an associated but not always easily identified cost. The process is outlined in the box. The costs associated with these stages can be considered under the following headings: direct excess service costs; infrastructure costs within NHS provider units participating in trials; central costs to organisations running trials; and general costs to the NHS. Some of these fall naturally on the NHS and others are appropriately funded through research organisations or the pharmaceutical industry.

How trial costs fit into these categories is explained below.

DIRECT EXCESS SERVICE COSTS

These costs can be identified and estimated for each trial. Examples and some problems which have been identified are listed here.

Costs of additional inpatient stays—One major childhood cancer centre has opted not to enter patients in the fifth study of the European Neuroblastoma Study Group because of the resource implications of the high dose intensity arm, which necessitates prolonged admission in hospital over the first few months of treatment.

Costs of additional treatments—The coordinating committee's trial of adjuvant hormone therapy in women with ovarian cancer has encountered problems because general practitioners are not prepared to prescribe hormone replacement therapy in the context of a trial. Several hospitals were unable to enter a Medical Research Council colorectal trial until a drug company stepped in to cover the cost of the experimental and standard drug. Other hospitals have been unable to participate in the adjuvant *x* ray and infusion study and in the anal cancer trial because of lack of radiotherapy time.

Costs of investigations—In the tamoxifen prevention trial some hospitals are not prepared to pay for the cost of the mammogram required before entry.

Costs of procedures—Problems have arisen in a trial evaluating colorectal screening that is being coordinated in Nottingham because general practitioner fundholders will not pay for referral for colonoscopy of volunteers with a positive result in a faecal occult blood test.

Costs of follow up—A consultant surgeon in Birmingham has been advised that it may be difficult to persuade purchasers to pay the bill for follow up. In

these cases—that is, trial follow up—the Medical Research Council and other bodies should take into account the financial consequences of their studies. General practitioner fundholders now have to pay for outpatient attendances and each follow up visit, and they are questioning the value of this.

Administrative costs—At least one hospital will not pay for dispensing a trial drug that was given by the drug company and provided ready packaged and labelled with the patient's name. Pharmacy charges are likely to be an increasing burden as the need to "balance the books" is extended.

INFRASTRUCTURE COSTS WITHIN NHS PROVIDER UNITS

Preparation of protocol—This can entail doctors' time in researching the background literature, attendance at meetings if collaborative groups are involved (often requires a full day if travel is necessary), writing of protocol and often grant application, taking the protocol to protocol review, seeking approval from local research ethics committee (often requires extensive photocopying and secretarial time and attendance at meetings by the doctor or prolonged correspondence to deal with any queries, or both).

Time spent with patient—Doctors and nurses have to spend extra time with patients to explain the trial and the randomisation process and seek informed consent. There may also be additional time needed after the patient has been entered into the trial.

Data collection—Doctors, nurses, and other staff have to collect information about the patient and record details of treatments given, side effects, etc, and follow up information. There is a trend towards reducing the amount of paperwork associated with large trials looking at survival end points (relying on mortality data from the Office of Population Censuses and Surveys). Increasingly, however, there is a demand for data on quality of life and health economics to be collected also. Quality of life is associated with long and complicated forms which have to be completed serially, and health economics is in its infancy in the context of cancer clinical trials and often requires detailed data collection.

Pathology and other review—In relation to the study of families with ovarian cancer one hospital was unable to allocate staff to search for records relating to research, although it was essential to confirm the diagnosis in the index case to determine risk in other family members. In the same study the trial centre has been asked to pay for the photocopying of extracts from patients' notes and in relation to one patient to pay for the technical work in retrieving the blocks and cutting the sections for pathological review.

CENTRAL COSTS TO ORGANISATIONS RUNNING TRIALS

The processing and analysis of data collected in the course of trials funded by research organisations is generally considered to be a central cost to that organisation and does not fall to the NHS. Research organisations also often provide dedicated data managers and secretarial and clerical staff who are responsible for the administrative aspects that are a major part of trials.

Trials are usually steered by a small group including clinicians, statisticians, etc, and progress is increasingly being monitored by data monitoring committees. The costs of servicing these small groups and of providing information to trialists are generally met by the research organisation.

For trials looking at mortality or incidence of cancer the central organisation often has to pay for flagging individual patients through the Office of Population Censuses and Surveys. This is not cheap, and it would reduce the costs of large trials greatly if flagging was provided free for nationally approved trials.

GENERAL COSTS TO THE NHS

Indemnity—This has become a major problem with the introduction of NHS trusts. It is clear that trusts cannot afford to take on the costs associated with providing indemnity, without which they will not allow trials to be conducted. Similarly, for those hospitals that do not have trust status there are no formal mechanisms for indemnity, and ethics committees will sometimes refuse permission for a trial because of this. One district has withheld approval for the tamoxifen prevention trial because of the lack of formal indemnity for the trial.

Registry information—The costs of maintaining data flow to the cancer registries is a central cost to the Department of Health.

A way forward: recommendations for change

The United Kingdom Coordinating Committee on Cancer Research recognises the difficulty of identifying substantial new funds and has focused its recommendations on possible ways of redistributing the existing allocation.

Firstly, it should be recognised that trials are an important part of cancer treatment and most, if not all, cancer treatment should be seen as part of the continuing trial process. The government should identify clinical trials in cancer as a priority. These should be seen as a form of prospective clinical audit. Clinical trials will identify inappropriate treatments. The resulting change in practice would lead to more cost effective strategies.

Secondly, adequate funds must be allocated to support the excess costs of running clinical trials and an effective mechanism developed for distributing them. No general practitioner, district, or trust should suffer financially because of their participation in collaborative trials. There are several ways of organising an allocation to trials.

(1) As service increment for teaching and research has not worked, radical change is necessary so that identifiable funds follow the patient in clinical trials.

(2) Purchasing authorities should be encouraged, when the optimal treatment is not known, to purchase treatment from centres where that treatment is given in the context of trials.

(3) Substantial funds are currently allocated to audit, and it should be recognised that evaluation of the effectiveness of treatment in the context of trials may be viewed as the most important form of audit, and a portion of the audit funds should be appropriately reallocated.

(4) Top slicing from the NHS should be considered to support nationally agreed clinical trials, which should be peer reviewed and carried out on a national basis by organisations such as the United Kingdom Coordinating Committee on Cancer Research, the United Kingdom Children's Cancer Study Group, and the Medical Research Council.

Thirdly, all indemnity for nationally approved clinical cancer trials should be provided centrally by the NHS and should not fall on individual hospitals or districts.

Fourthly, the authority to prescribe cancer treatment, particularly drug treatment, should be restricted to doctors who have received specific training. This should particularly apply to the use of medicines for unlicensed applications. There should be a staged licensing of new anticancer drugs, so that drugs will be licensed for approved phase 2 clinical trial; licensed for approved phase 3 clinical trial; and then licensed for general use. Any prescription on a "named patient basis" outside these categories would have to be paid for locally from non-contracted funds. Efforts should be made to encourage the pharmaceutical industry

to undertake trials through the national trials organisations that exist (such as the groups mentioned above).

Fifthly, doctors in training need to be trained in clinical trial methods and receive recognition for time spent doing this. The need for first author publications has in some cases led to the proliferation of small scale studies which meet this need but have limited value. A personal log book recording participation in national trials could be an alternative to the need for publications.

Sixthly, clinicians should have the right to have incorporated into their contracts sessional time allocated for participation in clinical trials, and this needs to be reflected in consultant job plans.

Seventhly, nurse counsellors should be provided for oncology units to encourage entry and facilitate the conduct of trials. Nurses are needed to help in the explanation of the details of treatment and the process of randomisation to patients. Doctors will continue to seek informed consent.

Eighthly, the research and development directorate should appoint someone whose role is to work with reputable organisations to facilitate the conduct of trials. For example, in providing advice on what information needs to be given to purchasers and providers. The Department of Health should organise the use of one standard proforma for all local research ethics committees.

Finally, the quality of cancer registry data should be improved. Pathology data should be linked directly to the registries. The Office of Population Censuses and Surveys should include information on tumour, stage, treatment, and outcome. There should also be cheaper access to survey data on outcomes so that the effects of new treatments could be monitored more easily.

The model which has been developed in Scotland (the Scottish cancer therapy network) to improve registration and entry into trials should be reviewed as a possible way forward for England.

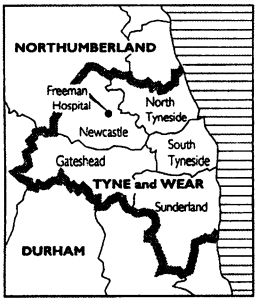
Members of the United Kingdom Coordinating Committee on Cancer Research are Cancer Research Campaign, Imperial Cancer Research Fund, Institute of Cancer Research, Leukaemia Research Fund, Ludwig Institute for Cancer Research, Marie Curie Memorial Foundation, Medical Research Council, Tenovus Cancer Fund. Observers: Department of Health, Scottish Home and Health Department.

1 Department of Health. *Assessing the effects of health technologies.* London: Department of Health, 1992.

NHS Update

Freeman Hospital: the will to survive

Sharon Kingman



This is the second article on our re-examination of the NHS reforms at the end of their third year

The future looks uncertain for the Freeman Hospital trust in Newcastle upon Tyne. There are plans to rationalise the health service in Newcastle by shifting resources from secondary to primary care, and by providing more services locally for people who live in the region but outside Newcastle. These could reduce the level of contracts that purchasers place with the trust in the future. Staff at the trust say the service they provide is good value for money, but purchasers do not seem to take this into account. Instead of choosing from a "shopping list" of priced procedures, purchasers are forcing the trust to dovetail its prices to meet their budgets. There is also concern at the potential impact on the trust's financial situation of reduced working hours for junior doctors and the Calman proposals on training.

Turbulent times lie ahead for the health service in Newcastle. The Freeman Hospital, now entering its fourth year as a trust, is coming to grips with the unpalatable realisation that a hospital's geographical accessibility to patients seems to count more than whether the treatment it offers is good value for money or of better quality.

No one at the Freeman any longer expresses surprise that—contrary to the government's promises when the NHS reforms were launched—the money does not follow the patients. The grim truth is that, once again this year, the purchasers want the trust to treat more patients for less money. And at the same time, purchasers in the region are making plans to divert more resources from secondary to primary care and to attempt to change general practitioners' referral habits so that patients obtain care closer to home, rather than travelling to Newcastle for it. Their choice will become restricted.

All this puts the trust in an unenviable position. If market forces are not allowed to operate, so that the cheapest and best hospitals attract more patients, and therefore more money, the lifeblood of the Freeman will drain away from it. For the first time since this series of articles began, people at the Freeman have begun to question whether the trust will survive in the future. After all, more than 70% of its patients currently come from outside the city.

In some ways, the past year has gone reasonably well. The Freeman has balanced its books. One of the costs of doing so was the loss of 68 staff—but this number was lower than the 100 job cuts that were feared to be in the offing at this time last year.

Gary Smith, chief executive of North Tyne Health (which represents North Tyneside and Newcastle Health Authorities), says the Freeman managed its contracts very well last year. Again, there was a price to pay: Mr Peter Wright, consultant general surgeon and the medical director of the trust, points out that sticking rigorously to the contracts has led to a large and rapidly building waiting list.

But look further than these simple objectives and you find uncertainty, discontent, and doubt. In radiology, for example, Dr Lakkur Murthy, clinical director, is wondering how much longer the department can carry on running at a loss. Radiology has a block contract with North Tyne Health to cover referrals by local general practitioners. It is based on the 1989-90 level of service.

"For the last three years," Dr Murthy says, "we have said to the purchasers, look at the actual activity, which is at least three times greater than in 1989-90. But so far they have not done so. We just want our costs to be met. They can't have something for nothing all the time."

The department's cumulative losses on this contract have now reached £100 000, Dr Murthy says. "We have given them a breakdown of what has been done

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