Rationing in action

EDITOR,—The *BMJ* recently sent me a copy of *Rationing in Action*.¹ At the conference that gave rise to the book I said that the health service is having to address the problems outlined in the book every day, as indeed it has had to since it was founded. We at the centre are helping to inform and when necessary steer the debate, and we welcome the continued input of academics, the medical profession, managers, and the public.

As everyone is covered by a universal and freely available health service the problem is one of setting priorities rather than sharing out resources. The pressures on health care will bring many of the issues further to the fore in the next few years: demographic pressures, improved medical technology, new types of treatment, and recognition of the rights of patients will all lead to greater pressure on resources and mean that the health service will need to be more flexible.

In my speech at the conference I emphasised that the government has a legitimate role in setting a strategy for health care. This inevitably leads to priority setting, to ensure a fair distribution of what is available. However, we can set only the framework in which local decisions are made: clinicians and managers must determine the health needs of local populations and how they are best met. These decisions are given legitimacy only when the views of patients and local needs are taken into account. Health professionals determine jointly with each patient his or her health needs and, in doing so, must make clinical decisions on the relative priority to be accorded to each patient. Thus it is essential that purchasers consult the public about planning and priorities, as well as general practitioners discussing treatment options with patients.

The government's role in this is to set the strategic and regulatory framework for providing health care, monitor the provision of care, provide information on clinical effectiveness, and ensure that decisions are made properly and fairly and take into account the needs and views of the population served. It is not the government's role to lay down local priorities or make local decisions; local purchasers and local providers of health care are best placed to do that.

The centre plays an important part in setting priorities. It must ensure that information about effectiveness is widely disseminated among purchasers and providers of health care. We have been carrying forward the important work, mentioned in my speech, on outcomes and effectiveness, and the information that emerges from this will enable health professions and those responsible for purchasing health care to order priorities on the basis of properly researched and validated evidence.

We have moved a long way towards ensuring that priorities are set on the basis of sound evidence about the effectiveness of interventions. In the book Ham discusses a range of approaches being taken in six districts.¹ All purchasers are having to consider how they determine local priorities. The fact that different approaches are used suggests that there is no place for national setting of local priorities when the determination of local needs is elusive, even to people living in the district.

Advice to authors

Priority will be given to letters that are less than 400 words long and are typed with double spacing. All authors should sign the letter. Please enclose a stamped addressed envelope for acknowledgment.

Setting priorities at almost any level is never straightforward. Klein points out that there is no "set of principles or techniques that will make our decisions for us" and that the best we can do in a changing environment is to make the process of setting priorities more rational.¹ Through our analyses of purchasing plans and the activity of purchasers we continue to monitor the way that this process is being developed at local level.

This is an important debate and is being held at all levels of the health service. *Rationing in Action* shows the wide range of opinion on setting priorities and rationing; by doing so it makes a valuable contribution.

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1 *Rationing in action*. London: BMJ Publishing Group, 1993.

Long term management after splenectomy

A national problem

EDITOR,—We wish to respond to the correspondence on our paper on the increased risk of sepsis after splenectomy.¹ We were saddened by Helena M Daly's letter.² We did not set out to audit individual clinicians but to identify why asplenic patients are still admitted to hospital and die with overwhelming pneumococcal sepsis. Since we submitted our data a further patient who had not received prophylaxis has died in Cornwall of pneumococcal sepsis. The data from Paul Kinnersley and colleagues³ and Sheena Reilly and colleagues⁴ confirm that this is a national problem. Our statement that "we do not know what advice—if any—they had been given" clearly referred to the six patients who died of pneumococcal sepsis. None of these patients were under Daly's care.

The initiative taken by Peter Baddeley and colleagues⁴ is welcome. Reilly and colleagues,³ R P D Cooke and colleagues,⁵ Peter J Flegg,⁶ and M Makris and colleagues⁷ all highlight important issues. In particular, Makris and colleagues draw attention to the uncertainty surrounding the use of prophylactic antibiotics. We acknowledged this in our paper but have elected to use prophylactic antibiotics until evidence from trials indicates that we should not. We think that the approach adopted by Makris and colleagues is equally valid. Our own policy, therefore, is to offer patients vaccination against pneumococcal, meningococcal, and *Haemophilus influenzae* infections. We believe that children should receive continuing antibiotic prophylaxis with penicillin, erythro-

mycin, or amoxycillin, while adults should receive the same for at least two years postoperatively. Selected "immunocompromised" groups of adults should also continue antibiotics for the rest of their lives. Educating patients about the risks that they face is the most important issue of all, and patients should have antibiotics at home to take in the event of infection.

We reiterate the need to establish protocols that clearly identify responsibilities for ensuring that all patients receive appropriate management. All patients already at risk who have not yet been identified need to be actively sought.

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- 1 Deodhar HA, Marshall RJ, Barnes JN. Increased risk of sepsis after splenectomy. *BMJ* 1993;307:1408-9. (27 November.)
- 2 Daly HM. Pneumococcal vaccine and splenectomy. *BMJ* 1993;307:1561. (11 December.)
- 3 Kinnersley P, Wilkinson CE, Srinivasan J. Pneumococcal vaccination after splenectomy: survey of hospital and primary care records. *BMJ* 1993;307:1378-9. (27 November.)
- 4 Correspondence. Long term management after splenectomy. *BMJ* 1994;308:131. (8 January.)

Monitor antibody levels after vaccination

EDITOR,—The role of the spleen in protecting against overwhelming sepsis due to encapsulated bacteria has long been established, and animal studies have shown the importance of the spleen in clearing organisms that have been opsonised by complement.¹ In animals that have undergone splenectomy the fixed macrophages of the liver take over this function, but high levels of specific capsular antibodies are required to facilitate hepatic clearance.² Vaccination in patients who have undergone splenectomy aims to maintain high specific antibody levels.

Mary McMullin and George Johnston emphasised the importance of vaccination against pneumococcus and possibly haemophilus and meningococcus in patients after splenectomy.³ They failed, however, to mention measurement of specific antibody levels after vaccination, which would show whether the patients have responded to immunisation. Since pneumococcal antibody levels may decline rapidly in some high risk groups it seems prudent to continue to monitor these antibody responses. We believe that some patients may need reimmunisation earlier than the recommended five years.

In our experience revaccination with pneumococcal vaccine may be associated with adverse effects: immunisation of 16 healthy adult volunteers resulted in erythema and pain at the site of the vaccination in three and an illness similar to serum sickness which lasted three days in one. Subsequently it was shown that the latter volunteer had had high pneumococcal antibody levels before vaccination. Measurement of specific antibody levels at least once a year would help to determine the most appropriate time for vaccination or revaccination.⁴

Measurement of specific antibody concentrations, though useful, does not give a true indication of the functional capacity of these

antibodies, particularly their opsonising activity. Assays are available in our unit to measure the ability of patients' serum to opsonise pneumococci and enhance the ingestion of these organisms by phagocytes. These tests may supplement quantitative antibody tests in determining the need for reimmunisation.

As pneumococcal vaccine contains capsular polysaccharide from only 23 serotypes of *Streptococcus pneumoniae* it does not provide full protection against pneumococcal septicaemia, and lifelong prophylaxis with antibiotics must be recommended. The reported incidence of pneumococcus that is resistant to penicillin, however, is over 40% in Spain,⁷ which makes it crucial to recommend antibiotics resistant to penicillinase for high risk patients.

Finally, *Capnocytophaga canimorsus* must be added to the list of organisms of which people who have undergone splenectomy and have contact with animals should be aware. This organism can be transmitted by animal bites, especially dog bites, and can lead to septicaemia and death. It remains susceptible to penicillin.

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- 1 Hazelwood M, Kumararatne DS. The spleen? Who needs it anyway? *Clin Exp Immunol* 1992;89:327-9.
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- 3 McMullin M, Johnston G. Long term management of patients after splenectomy. *BMJ* 1993;307:1372-3. (27 November.)
- 4 Lortan JE. Management of asplenic patients. *Br J Haematol* 1993;84:566-9.
- 5 Casal J, Fenoll A, Vicioso M, Munoz R. Increase in resistance to penicillin in pneumococci in Spain. *Lancet* 1989;i:735.

Revaccination may cause relapse

EDITOR,—Merck Sharp & Dohme has amended the datasheet for pneumococcal vaccine (Pneumovax II) to include a section on revaccination.¹ This brings it into agreement with the recommendations of the Department of Health that patients who have had a splenectomy (among others) should be considered for revaccination. The original diagnosis warranting splenectomy does not seem to have been considered in these recommendations, and I fear that some patients may be more at risk than others of suffering adverse reactions.

A 29 year old patient under my care had developed idiopathic thrombocytopenic purpura as a child and had had a splenectomy when he was 5. Since he was 21 he had suffered several episodes of thrombocytopenia and developed autoimmune haemolytic anaemia. He was vaccinated uneventfully with pneumococcal vaccine in June 1990. In February 1993 he was inadvertently revaccinated by his general practitioner and two days later he became ill with appreciable haemolysis and thrombocytopenia.

Revaccination probably precipitated his relapse,² and although the interval between the first and second vaccination was shorter than that recommended in the new datasheet and by the Department of Health, more cases like this one may occur as revaccination becomes more widespread. Although the risk of pneumococcal infection may be considered to be greater than those of precipitating a relapse of immune haemolysis or thrombocytopenia, the possibility of a relapse should be taken into account when patients with autoimmune haematological disorders are revaccinated.

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- 1 Graham RCA. Long term management after splenectomy. *BMJ* 1994;308:133. (8 January.)
- 2 Dacie J. *The haemolytic anaemias*. Vol 3. Edinburgh: Churchill Livingstone, 1992:370.

Cancer in nuclear test veterans

Important questions unanswered

EDITOR,—S C Darby and colleagues' paper on the health of people who participated in British nuclear tests omits some fairly basic information.¹ In a study of this kind it would be reasonable to present a breakdown of the study group by age, sex, and social class.

The paper argues that the relative risk of leukaemia between participants in the tests and controls was "principally due to the scarcity of cases in the control group and may have been due to chance." No figures are produced to back up this assertion, although it must be fairly easy to estimate the probability of a group of 22333 men having a standardised mortality ratio for leukaemia of only 0.32 by chance. The approach used calls into question the whole point of having a control group if the authors can call into question its reliability.

The measurements of radiation exposure also raise questions. The paper states, "Information on film badges issued at the tests was made available by the Ministry of Defence for 5686 men." This is only 26.6% of the study group. It seems odd that only a quarter of people potentially exposed should be issued with film badges in an experiment on the effect of nuclear weapons on soldiers. If, on the other hand, fuller data exists in the Ministry of Defence's files, on what basis were the data that were made available chosen? This is important, for these data are quoted as one of the main reasons that authors question the causal hypothesis.

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- 1 Darby SC, Kendall GM, Fell TP, Doll R, Goodill AA, Conquest AJ, et al. Further follow up of mortality and incidence of cancer in men from the United Kingdom who participated in the United Kingdom's atmospheric nuclear weapons tests and experimental programmes. *BMJ* 1993;307:1530-5. (11 December.)

Statistical analysis inappropriate

EDITOR,—S C Darby and colleagues' study of cancer and atmospheric nuclear weapons tests raises some interesting methodological questions.¹ Exposed servicemen and civilians working with nuclear weapons were compared with a control group matched for age and occupation and with the general population by means of national mortality statistics. Two sided tests and 95% confidence intervals were used to compare the exposed group with the general population. One sided tests and 90% confidence intervals were used to compare the exposed group with the control group. The tests were done in the direction of the observed difference.

In a one sided test the alternative hypothesis is that there is a difference in a specified direction. The null hypothesis is then that there is no difference or a difference in the opposite direction. This is reasonable if a difference in the opposite direction would have the same meaning or result in the same action as would no difference. For the comparison with the general population it could be argued that the exposed group, predominantly servicemen, were selected to reduce the risk of cancer. Men with genetic conditions that might predispose to cancer, such as Down's syndrome, were excluded, but they were included in the general population. Thus it would be expected that if the exposure had no effect the incidence of

cancer in the exposed group might be less than that in the general population, by an unknown amount. Fewer cancers than expected in the exposed group would have the same interpretation as no difference, a phenomenon known as the "healthy worker effect." It might be argued that carrying out a one sided test in the direction of more cancers in the exposed group would be appropriate.

For the comparison with the control group this argument does not hold. The controls were chosen so that the risk would be the same apart from any risk due to the exposure. Thus an excess of cancer in the control group would be surprising and lead to the conclusion either that the radiation exposure protected against cancer or that the groups were not comparable. If no difference was found, on the other hand, the conclusion would be that there was no evidence that the radiation influenced the risk of cancer. The conclusions would be different, and a one sided test in the direction of more cancers in the exposed group cannot be justified.

It is even harder to justify a one sided test in the direction of fewer cancers in the exposed group, which is opposite to the research hypothesis. To test in the direction of the observed difference is in fact to carry out tests in both directions simultaneously. As one of these tests assumes that fewer cancers in the controls is equivalent to no difference and the other assumes that more cancers in the controls is equivalent to no difference the tests are contradictory. The procedure is the same as a two sided test at the 10% level and this is not truly one sided at all. Several of the "significant" differences in table IV would disappear at the conventional two sided 5% level.

Though it is not essential to use the arbitrary 5% as the decision point in tests of significance, departures from this convention should be stated clearly, which this paper does not do.

Use of a 10% significance level in place of the usual 5% level does not alter the main conclusions of this paper. In others, however, it might, and the *BMJ* is rightly regarded as a model for medical researchers. I hope that we will not see a rash of one sided tests in the direction of the difference in the future.

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- 1 Darby SC, Kendall GM, Fell TP, Doll R, Goodill AA, Conquest AJ, et al. Further follow up of mortality and incidence of cancer in men from the United Kingdom who participated in the United Kingdom's atmospheric nuclear weapon tests and experimental programmes. *BMJ* 1993;307:1530-5. (11 December.)

Authors' reply

EDITOR,—Our paper describing the mortality and incidence of cancer in participants in nuclear tests was a summary of our findings. The full details, as we stated, were given in an accompanying report published simultaneously.¹ Most of the information requested by Richard Lawson is given there, and we repeat some of it here.

Lawson asks for a breakdown of the study group by sex, age, and social class. Only men were considered, as we knew of too few women participants for useful study. The table shows the distribution of the participants and their controls by service or employer, rank or social class, and whether or not they were on national service. The distribution in the two groups was closely similar; so was the distribution by year of birth, year of enlistment or employment, and year of discharge or termination of employment.²

Overall, the mortality in the control group was much as would have been expected because of the high proportion of officers and the limitation to men fit for service abroad, with standardised mortality ratios of 0.81 and 0.83 for all causes of death and all deaths due to neoplasms, respectively, in the original period of observation (to the end of