

QUALITY-ADJUSTED LIFE-YEARS

SIR,—Professor Smith's thoughtful essay (May 16, p 1134) contains some misconceptions about quality-adjusted life-years (QALYs) and fails to consider the issues in their proper context.

Smith asserts that with the QALY approach "old and very sick patients will be placed . . . in a position of double jeopardy" and resources will be denied to "those who most need them". He also observes that "the use of a quantitative algorithm obscures, but does not avoid, the arbitrary assessment of the value of one person's life by others". The QALY approach is a way of measuring the relative value of health benefits; the issue is not how old or sick patients are, but how much better can we make them. Hip replacements come out well on QALYs, yet they are for older, disabled patients. If Smith means that resources will not necessarily go to the people who are oldest and sickest, he is right. The old and seriously ill do not "need" treatments which do them no good. So where is the problem? Is it that because old people generally have less life expectancy than young people they will in some cases benefit less from treatment than young people will? If so, this seems to be a matter which hitherto medical science has accepted without much ado. For example, the use of survival rate at, say, two years as a criterion for choosing between treatments usually discriminates against the older and sicker patients. Furthermore its use might be taken to imply that to survive less than two years is of no value, that survival beyond two years is of no value, that it does not matter with what quality of life you survive to two years, and that it does not matter who you are. The only one of these four propositions that seems ethically defensible is the last one, and that is the very one that Smith is attacking in the QALY context.

In the QALY calculations I have done I have taken it that one year of additional healthy life expectancy is regarded as of equal value to everybody. This is "arbitrary" in the sense that alternative positions could be taken, but has the advantage of reflecting the view that medicine should not discriminate between people on grounds of age, sex, wealth, social position, virtue, race, religion, and so on. But if it were decided to use the distribution of health (as opposed to health care) as a compensatory mechanism for the maldistribution of income, education, housing, employment, and the like there is nothing in the QALY methodology to stop you doing so. The moral and practical implications of such a compensatory policy would have to be thought through carefully, and the QALY approach, far from "obscuring" these issues, brings them out into the open.

Smith is worried that the QALY approach may be dangerously beguiling to managers because it is simple, mechanistic, and "an apparently automatic decision making device", which will replace "responsible political discussion". I see the problem as almost the opposite. The easiest and most mechanistic way of making decisions is to ignore the impact of decisions on QALYs and simply make resource cuts across the board. To ask decision makers to work through the implications of their decisions for people's life expectancy, disability, and distress seems to me to be asking them to make decision making much more complex, demanding, and agonising, and it is a political responsibility they may well prefer to shy away from. What is so wonderful about current decision making that is going to be so adversely affected if politically responsible people start thinking systematically about QALYs?

It is important for community medicine specialists to adopt a constructive (even if guardedly critical) stance on the QALY methodology because it provides a framework in which to bring their own knowledge and skills to bear upon management decisions in the National Health Service. The QALY approach is data hungry, requires teamwork, and it has the potential to integrate clinical and managerial approaches to decision making. This ought to resolve some of the tensions and suspicions which permeate the system at present, and to do so in a manner which will leave the NHS in better shape and, more importantly, the population at large in better health.

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SIR,—Professor Smith argues that there are several, often unrecognised deficiencies in using QALYs to make decisions about the allocation of health-care resources. In evaluating the QALY concept we need to distinguish between "theoretical plausibility" and "empirical validity". Smith correctly takes issue with the theoretical plausibility of the concept, but neither provides evidence for nor disputes its empirical validity. Studies on the quality of life of patients with end-stage renal disease support the empirical validity of the QALY approach.

Our studies have consistently revealed a strong correlation between the number of days per year people are willing to forego in return for good health and their subjective and objective quality of life assessments.¹⁻³ For example, patients on hospital haemodialysis who scored at or above the mean on an index of wellbeing were willing to give up 22 days per year (higher score = greater wellbeing) while patients scoring below the mean were willing to forego 50 days. Among kidney transplant recipients, those scoring at the mean or above were willing to forego 8 days, while those scoring below the mean were willing to give up 36 days per year. The results were similar for objective indices such as the Karnofsky index. Haemodialysis patients who were least debilitated were willing to give up 22 days per year in return for good health, while debilitated patients were willing to forego 46 days. Among transplant recipients, the least debilitated patients were willing to forego 10 days per year, while functionally impaired patients were willing to give up to 40 days.

These results, and those from other studies, suggest that the QALY concept has empirical validity. Whether or not it is an acceptable basis upon which to allocate health care resources remains debatable.

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SIR,—Professor Smith points to the difficulties of developing a set of quality adjustment fractions and states that no attempt has been made to construct the required ratings on the basis of any sampling of general opinion. Such measurements were made on the general public as early as 1978,¹ and one recent study incorporates quality assessments made by a general population sample.² Furthermore, the form of question Smith prefers ("To what extent would you accept a shortening of your present expectation of life as the price for a complete restoration of health if that were possible?") is precisely the form embodied in the "time trade-off technique" for estimating quality of life variations,³ an approach developed and tested over several years by research-workers in North America.

Smith notes that a choice of whom to treat based on any form of cost-effectiveness assessment will always favour patients whose age or disease confers the prospect of longer and better-quality survival and that an individual has a right to curtail an insufferable existence where this is technically possible. However, in health service planning it is not possible to meet all needs with limited resources. Hospital waiting-lists in the UK demonstrate that a health care system can coexist with pain and suffering without calculating QALYs. What the QALY approach might do is help us ameliorate more pain and suffering in total, given the limited resources available.

I agree that decisions in health care are made essentially at two levels, the planning level and the clinical level.⁴ The main application of QALYs is in planning, but the approach may also be relevant in the discussion of treatment decisions with the individual patient. Indeed, in many clinical settings the process of informed consent has to embody some mechanism for exploring the patient's trade-offs between quantity and quality of life.

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LICENSING WORK ON IVF AND RELATED PROCEDURES

SIR,—It is unfortunate that your May 16 editorial on the 1987 report of the Voluntary Licensing Authority for Human in Vitro Fertilisation and Embryology (VLA) could lead one to believe that we have flouted the VLA's 1986 guidelines. We have not—indeed, how could we have “disregarded two of the VLA's new guidelines”, which were made known to us only on May 6?

The VLA granted a licence to this unit knowing that we intended to continue with a flexible policy on the number of embryos transferred, based upon the particular circumstances in a given infertile couple's case, and our statistical data support this rationale. We agree with your view and that of the Warnock Committee that this decision should remain one of clinical judgment.

We agree that one could be excused from concluding that the new guidelines have been drawn up in an attempt selectively to restrict the clinical freedom of a specific group of doctors since there has been no public censure of others, some of whom have also given treatments now considered inadvisable (eg, sister-to-sister oocyte donation and selective reduction).

All that has happened is that the VLA has gone beyond its declared terms of reference so that our unit has now been declared “off side” even though the VLA's new guidelines have only “moved the goalposts”. The number of embryos for transfer, formerly only a recommendation, has now become a rule, as indeed has the number of oocytes for transfer by GIFT, which does not fall within the VLA's terms of reference, which relate specifically to IVF research.

Your editorial is correct in indicating that the VLA and the Warnock Committee recommended that gamete donors should ideally be anonymous but both agreed that known donors may be used in exceptional circumstances. This is our policy, hence our distress at public censure. We still feel there is a case for both anonymous and known donors, who must be carefully counselled. The use of known donors is especially relevant to some ethnic groups, and to dismiss their aspirations would be unfortunate, especially since there is no evidence to support the view that subsequent emotional disturbance in resultant children is any greater in these circumstances. The problem really is one of perception since it is no more appropriate to consider an oocyte donor as a genetic “mother” than it is to consider a sperm donor as a genetic “father”. Donors provide gametes and a mother bears her child.

We share the VLA's concern that another Private Member's Bill could restrict assisted reproduction treatment and research into improving success rates. However, we differ on the perceived public anxieties, on how we should present our case, and on the terms of reference and constitution of any statutory authority. We feel that some members of the public and our profession will be suspicious of any organisation or body which might be subject to criticism for appearing to adopt double standards.

Why should doctors not be allowed to use their clinical judgment in the best interests of an infertile couple when they are expected to do so for every other aspect of medicine? Surely patients have a right to be involved with a clinical decision affecting their care or whether or not they agree to studies being done on biological material made available for research. Similarly, if the VLA feels that selective reduction should only be done for clinical reasons such as malformation or ectopic pregnancy, others could question whether the 143 580 abortions in 1986 were also done for comparable medical, as opposed to social, reasons.

We role of the VLA needs to be reassessed and its guidelines redrafted for these are in essence rules, and the current document

weakens rather than strengthens the case for helping the infertile and, indeed, for undertaking and supervising the necessary research. It would be ironic if doctors were to have more clinical freedom under Mr Enoch Powell's intended legislation than under the VLA's guidelines.

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SIR,—As a physician concerned with reproductive endocrinology and ovulation induction, and as one who has referred patients to Professor Craft, I read with interest his joint letter. The first patient I referred to his unit for GIFT had six ova replaced, resulting in a quadruplet pregnancy. The outcome has apparently been satisfactory for the mother and all four offspring, but this experience has reinforced me in the view that no more than three eggs should be replaced in GIFT or three embryos in IVF. Craft and colleagues state that their duty is to give an infertile couple the best chance of achieving and maintaining a pregnancy. This is surely too limited and narrow a view. Not only do the risks to the mother and fetuses go up exponentially with increasing fetal numbers, but so do the costs to the National Health Service, even when, as in the above case, the outcome is apparently satisfactory. Surely their unit also has a responsibility to ensure that the babies produced do not run unnecessary risks and that their policy does not overload the facilities of special care baby units, and so prejudice the life and health of other infants who are competing for the same facilities? It seems obvious that any more than twin pregnancy is to be avoided if at all possible (and certainly would be if the private clinics responsible for producing these multiple pregnancies had to bear the cost of caring for the resulting premature babies).

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SIR,—We read with interest your May 16 editorial and the accompanying letter from Professor Craft and his colleagues about in-vitro fertilisation (IVF) and the issue of multiple embryo transfer.

The proportion of all maternities in England and Wales resulting in triplets and higher order births started to increase in the late 1970s.^{1,2} A higher order birth is likely to give rise not only to problems for all those responsible for the care and welfare of the children neonatally and subsequently but also to social strain on the household in which they live. Substantial economic costs coupled with the burdens of hours spent in child care can be unexpected and overwhelming.

There is neither structured provision for, nor yet any systematic appraisal of, these possible social and economic consequences. The Department of Health and Social Security's small grants scheme is funding a study of the parents of triplets and higher order births which will provide the first population-based data on the problems faced by those responsible for such children. This national study, on which we are engaged, is concerned with triplet and higher order births registered in England and Wales in 1979-85 (except for 1981). Complementary surveys, collecting information from obstetricians, paediatricians, and other specialists and from general practitioners relating to the same population, are being undertaken by the Office of Population Censuses and Surveys and the National Perinatal Epidemiology Unit. The issue of whether the problems and outcomes vary if the multiple pregnancy occurs spontaneously or after medical assistance is one interest of our research. Pilot work in the north and south of England has revealed a striking variation between different health and local authorities in relation to the provision of community nursing and domiciliary services.

Johnston and her colleagues³ have investigated the stress and judgments under uncertainty experienced by couples on an IVF/ET programme. They emphasise the disproportionate impact of media reports of successful outcomes. In assessing the risks of a multiple pregnancy it is important to consider both the social and the psychological aspects.