Letters

Are research ethics committees behaving unethically?

Committees are now being expected to do everything

EDITOR—I read Julian Savulescu and colleagues' article on local research ethics committees with a sinking heart.[1] The view presented seems to be part of a growing movement towards placing increased responsibility on local research ethics committees, which are now expected to assess the need for each new project (against the background of previous related research), interview researchers, inspect sites, monitor progress, and follow up the reporting of all completed trials.

The desire to improve the quality of medical research is laudable, but it is unreasonable and unrealistic to expect this to be done entirely through the mechanism of review by local research ethics committees, at least as presently set up and funded. Members of local research ethics committees carry out their functions on an amateur basis (though some have professional backgrounds). They would not pretend to be omniscient, only conscientious, sincere, and disinterested. Their review forms only one safeguard in research.

To undertake the additional tasks suggested in the article, local research ethics committees would need a great deal of extra time and training, and they might well expect to receive remuneration commensurate with their new accountability. Even if these changes were desirable they would be difficult to implement.

It is surely better, pending such changes, to divide responsibility among the various groups involved. Decisions about the need for particular trials, which have to be based on an assessment of research so far undertaken in similar fields, should be made by the appropriate staff in the pharmaceutical companies or the research organisations or, in the case of students, by their academic tutors. To these groups of people should also fall the responsibility of monitoring the conduct of the research. Responsibility for ensuring the full reporting of the outcomes of a trial, on which Savulescu and colleagues lay emphasis, would be difficult to allocate, because—in the case of research sponsored by pharmaceutical companies—there are protected commercial interests.

Such divided responsibility ensures that the role of local research ethics committees can be limited to what it was originally intended to be and what they can perform under present conditions.

E Pierce *Administrator, Brighton Local Research Ethics Committee*
East Sussex, Brighton, and Hove Health Authority, Lewes BN7 2PB

1 Savulescu J, Chalmers I, Blunt J. Are research ethics committees behaving unethically? Some suggestions for improving performance and accountability. *BMJ* 1996; 313:1390-3. (30 November.)

Committee would not consider application before payment of £100

EDITOR—Julian Savulescu and colleagues ask whether research ethics committees are behaving unethically.[1] An extension to this question is whether ethical committees are behaving unethically by insisting on the payment of a fee before they will look at a research application, especially if the project is to be assisted by a pharmaceutical company. On asking for the reason for the imposition of a charge of £100 before the committee of a non-university hospital trust would consider my application, I was told that it was to cover the paperwork and that "the drug company can afford it." There was little paperwork to be dealt with, because applicants have to provide copies of the application for the members of the committee, and no other reason was given. I found that the ethics committee has no fundraising status and that the chairman had no idea what the money would be used for, other than to suggest, facetiously, that the committee would have a party. I gather that other hospitals are also now making a charge.

Apparently the philosophy of making money at all levels in a trust hospital is becoming an obsession, even if no one knows what to do with the money when it has been collected. Is this obsession spreading to other committees? What of the ethics? Are we so cynical that we have lost our altruism?

John Tomlinson *Honorary senior lecturer, University of Southampton*
Clays Farm, East Worldham, Alton GU34 3AD

1 Savulescu J, Chalmers I, Blunt J. Are research ethics committees behaving unethically? Some suggestions for improving performance and accountability. *BMJ* 1996;313:1390-3. (30 November.)

If committees were sued who would be liable?

EDITOR—Julian Savulescu and colleagues are not the first to question the behaviour of local research ethics committees and to ask that their approach be better defined and better standardised.[1] The authors have, however, taken an important and unhelpful step in emphasising that committees should be held "accountable" for allowing "two forms of scientific malpractice to occur: the execution of unnecessary, sometimes harmful, research and the failure to ensure that the results of research are publicly accessible."

Members of ethics committees get no payment for their work. Neither do they get much thanks, though complaints are common enough. Now it seems that ethics committees must brace themselves to be sued, the plaintiff's lawyers using Savulescu and colleagues' article in support of their case when someone is harmed by unnecessary research or because a paper was not published.

Much of the research done in hospitals in Britain is multicentre research. Ethics committees are caught between pharmaceutical companies, investigators, and ethical pressures. The motive of the companies is ultimately profit. Researchers have a range of motives, among which is looking on research merely as a means to clinical advancement. Many of the problems of poor medical research described by Savulescu and colleagues are due to these motives; ethical pressures would be better directed

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Advice to authors

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When deciding which letters to publish we favour originality, assertions supported by data or by citation, and a clear prose style. Letters should have fewer than 400 words (please give a word count) and no more than five references (including one to the BMJ article to which they relate); references should be in the Vancouver style. We welcome pictures.

Letters should be typed and signed by each author, and each author's current appointment and address should be stated. We encourage you to declare any conflict of interest. Please enclose a stamped addressed envelope if you would like to know whether your letter has been accepted or rejected.

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towards these motives and support given to ethics committees in their difficult task. This is an imperfect world, and impatience with its imperfections is least well directed at those who feel most beleaguered.

When we are sued who will be liable? Will it be the health commission, chairperson of the committee, whole committee, or member? Or will we simply decide that the whole thing is not worth the effort and resign? There are plenty of other things we could do with the time.

Neville W Goodman *Member, Southmead Medical Research Ethics Committee*

Alaisdair MacGowan *Chair, Southmead Medical Research Ethics Committee*
Southmead Health Services, Southmead Hospital, Bristol BS10 5NB

1 Savulescu J, Chalmers I, Blunt J. Are research ethics committees behaving unethically? Some suggestions for improving performance and accountability. *BMJ* 1996; 313:1390-3. (30 November.)

Corporal punishment must not be reintroduced into schools

EDITOR—Members of the child protection interest group, a subgroup of the British Association of Community Child Health, were appalled to hear that the reintroduction of corporal punishment is to be debated in the Education Bill. Beating is a part of the vision that the secretary of state for education and employment has for education in Britain. Hitting or beating was abolished in state schools in 1987, and a generation of children has grown up without fear of the cane, ruler, tawse, ferule, slipper, or hand.

Since 1987 the British government has been a signatory to the UN Convention on the Rights of the Child. The section of the convention referring to the protection of children from violence (article 19) states, "Children and young people have the right to physical and personal integrity. All services should ensure that child protection is based on this right and that definitions of abuse do not condone any level of violence to children." What is proposed in the Education Bill is not the "gentle or loving smack or tap" approved by Archbishop Carey[1] but beating: an adult would deliberately, with an implement, inflict pain on a less powerful and usually smaller person.

Interestingly, most private schools no longer use physical punishment. Is this because it has been found ineffective? The only excuse for hitting is that is helps children to become better disciplined. In 1989, however, the government commissioned the Elton inquiry into discipline in schools, which reviewed recent studies; it found that punitive regimes, particularly those that used corporal punishment, tended to be associated with worse rather than better standards of behaviour.[2] The statement that "no one likes hitting" is unfortunately untrue: the sexual connotations for the beater and beaten are well recognised.

As doctors we should work towards a less violent society. Physical abuse of children often begins as physical chastisement that the carer admits went "too far." The organisation EPOCH (End Physical Punishment of Children) shows that children do not have to be hit to be disciplined, and the Gulbenkian Foundation's *Children and Violence* is a comprehensive source book of what is known and suggests ways forward, including the outlawing of physical punishment.[3] The Royal College of Paediatrics and Child Health opposes all physical punishment but would prefer education for parents to legislation. The National Commission into the Prevention of Child Abuse has called for the repeal of the law, over 50 years old, that allows parents to use "reasonable chastisement."[4]

We urge the government to take note of the views of those committed to the better care of children and teenagers.

On behalf of 62 members of the child protection interest group

Jane M Wynne *Consultant community paediatrician*
Community Child Health, Leeds LS2 9NP

1 Gledhill R. Archbishop says a loving slap can be good for children. *Times* 1996 Oct 26.
2 Department of Education and Welsh Office. *Discipline in schools: report of the committee of inquiry.* London: HMSO, 1989.
3 Gulbenkian Foundation. *Children and violence: report of the commission on children and violence.* London: Gulbenkian Foundation, 1995.
4 National Commission of Inquiry into the Prevention of Child Abuse. *Childhood matters.* London: NCIPCA, 1996.

Cancer units are implementing changes from generic to specialist practice

EDITOR—The *Policy Framework for Commissioning Cancer Services* produced by the chief medical officers of England and Wales, with equivalent documents in Scotland and Northern Ireland, recommends appreciable changes in the provision of cancer services.[1] The report introduces a network of services linking primary care, cancer units, and cancer centres. The concept of cancer units is new and requires changes in clinical organisation.[2] Implementation of this policy demands an increase in clinical or medical oncology sessions at unit level to a minimum of five weekly sessions. A survey by the Royal College of Radiologists in 1991 found an average of only 1.8 clinical oncology sessions a week in general hospitals.[3]

In March 1996 a questionnaire was sent to medical directors of acute trusts in England (trusts providing radiotherapy services or that were part of a proposed cancer centre were excluded). They were asked to supply, firstly, the number of regular fixed sessions provided by consultants in clinical or medical oncology, or both, in a typical working week in March 1995 and March 1996 and planned for March 1997; and, secondly, the number of clinical or medical oncologists, or both, involved. The response rate was 90% (113/125). There was regional variation, the lowest response being 77% (17/22).

Medical and clinical oncology sessions are increasing towards the target (table 1). The most common sessional arrangement in 1995 was, in order, two sessions, three sessions, and one session a week. If all planned sessions are achieved this will become five, three, and two sessions by March this year. Sixty four respondents planned increases in 1996-7. Two thirds (30) of trusts below the median in March 1996 and half of those above the median intended to increase sessions. Almost all trusts (111) reported that posts were linked with a centre or radiotherapy hospital. In 61 trusts all the sessions were provided by visiting clinical oncologists, three trusts used only medical oncologists, and 49 trusts used a mixture. Three respondents were unaware of the difference between these specialties.

The implementation of the new policy requires a shift from generic to specialist practice, which will increasingly be within multidisciplinary clinical teams. The low number of non-surgical oncology sessions in many hospitals inhibits the growth of effective multidisciplinary management of common cancers, without which clinical decisions will not always be fully informed. Recent increases in non-surgical oncology sessions together with the additional sessions planned shows that many units intend to reach the recommended target. Although limitations of finance and the supply of suitable candidates will slow this process in practice, the commitment is encouraging.

R A Haward *Professor of cancer studies*

Ziv Amir *Senior research fellow*
Yorkshire Cancer Organisation, Cookridge Hospital, Leeds LS16 6QB
rah@yco.leeds.ac.uk

1 Expert Advisory Group on Cancer to the Chief Medical Officers of England and Wales. *Policy framework for commissioning cancer services: a report.* London: HMSO, 1995.
2 Haward RA. Establishing cancer units. *Br J Cancer* 1995; 72:531-4.
3 Royal College of Radiologists, Board of the Faculty of Clinical Oncology. *Medical manpower and workload in clinical oncology in the United Kingdom.* London: RCR, 1991.

Table 1 Number of non-surgical oncology sessions in 113 potential cancer units in England

	Actual		Planned
	March 1995	March 1996	March 1997
No of sessions:			
Mean	3.54	4.12	5.91
Median	3.00	3.00	5.00
Total	400.3	461.8	582.0
No of trusts with ≥5 sessions/week	23	35	63

Home births

Difficulties arise when women choose not to take advantage of professional help

EDITOR—The Northern Region Perinatal Mortality Survey Coordinating Group, reporting perinatal loss in planned and unplanned home births, found a much greater hazard associated with unplanned delivery outside hospital.[1] We wish to report a similar analysis of data from the Cardiff births survey for the years 1991-5.[2]

During this period there were 28 626 deliveries to residents of South Glamorgan. We excluded 992 that were planned deliveries outside the area and 85 in which the actual delivery was outside the area, leaving 27 549 deliveries. We excluded 32 deaths due to congenital abnormalities and 1985 deliveries in which the birth weight was less than 2500 g, leaving 25 532 deliveries. In 83 deliveries the birth weight was unknown, which left 25 449 deliveries for analysis.

One hundred and thirty seven women planned to deliver at home. No perinatal or neonatal deaths occurred in the 94 who did deliver at home. In the 43 transfers to hospital for delivery one stillbirth occurred. There were six deliveries at home to women who had made no arrangements for professional care during pregnancy or labour, representing 2% (6/346) of all home deliveries. In this group two stillbirths occurred; both the babies were apparently full term but the deliveries were unattended.

These data support the view that planned home delivery can be just as safe as hospital care. The difficulties arise when women, for whatever reason, choose not to take advantage of professional help. It is thus difficult to see how health authorities purchasing maternity care can provide for these women as recommended by the Northern Region Perinatal Mortality Survey Coordinating Group.

Susan C Thomas *Midwife informatics codirector, Cardiff births survey*
c/o Directorate of Women's and Children's Health, Llandough Hospital, Penarth CF64 2XX

Jacqueline A Bethel *Clinical databases manager*
Department Medical Computing and Statistics, University of Wales College of Medicine, Cardiff CF4 4XN

1 Northern Region Perinatal Mortality Survey Coordinating Group. Collaborative survey of perinatal loss in planned and unplanned home births. *BMJ* 1996; 313:1306-9. (23 November.)
2 Andrews J, Davies K, Chalmers I, Campbell H. The Cardiff births survey. In: Harper PS, Sunderland E, eds. *Genetic and population studies in Wales.* Cardiff: University of Wales Press, 1986:317-41.

More evidence is required on most effective means of providing newborn examination

EDITOR—The Northern Region Perinatal Mortality Survey Coordinating Group and J Davies and colleagues report low perinatal mortality in planned home births but a reluctance among general practitioners to support such births.[1 2] The issue of who examines the newborn baby after home birth was not addressed. In the inner London borough of Tower Hamlets there are reports of parents taking their baby from home to hospital or relying on the untrained midwives examination because some general practitioners are reluctant to provide this service. Parents were not always informed of this before the birth.

Table 1 Views of general practitioners in Tower Hamlets about provision of newborn examination for babies born at home

	All (n=74)	Men (n=40)	Women (n=34)	P value for men *v* women
Examination should be performed within 24 hours (n=70)	27	10	17	0.064*
Happy to do examination in surgery hours (n=72)	65	33	32	0.12†
Happy to do examination at weekends (n=65)	27	9	18	0.035*
Happy to provide examination at home (n=71)	54	23	31	0.003†
Happy for women to have home births (n=74)	56	23	33	<0.0001†
Agree with local information leaflet about maternity services provided by general practitioners (n=71)	49	22	27	0.055*

*χ^2 Test with Yates's continuity correction. †Fisher's exact test.

To ascertain general practitioners' views about the provision of the newborn examination after home birth and their willingness to have details of the maternity service that they provided included in a local information leaflet, a postal questionnaire was sent to all 104 general practitioner principals working in Tower Hamlets in January 1996. Replies were received from 74 (71%) (34/38 (89%) women compared with 40/66 (61%) men (P = 0.004)). Table 1 summarises the respondents' views.

General practitioners happy for women to have home births were significantly more likely to provide the newborn examination at weekends (26/49 (P = 0.001)) and to agree with an information leaflet (43/55 (P = 0.004)) than those who were unhappy for women to have home births. Doctors who were unhappy for women to have home births expressed concerns about the increased workload, the medicolegal consequences of home birth, the need to be trained in child health surveillance, and increasing the demand for home birth by providing information.

Changing Childbirth states that local information about maternity services should be available for all women,[3] but a third of our sample did not agree with this. Respondents preferred trained midwives rather than general practitioners or paediatricians to examine newborn babies and supported abandoning the current tradition of examining the baby within 24 hours of birth. The Joint Working Party on Child Health Surveillance suggests that the timing is not critical and that the service provided should be decided locally.[4] General practitioners are obliged to perform the newborn examination only if they have contracted with the woman to provide maternity services.[5] Since they need not be on either the local obstetric or child health surveillance register, their skills may vary. Our study suggests that out of hours workload, attitude to home birth, and the sex of the general practitioner rather than objective evidence are likely to determine the services provided. Robust evidence is required to inform national policy on the most effective means of providing the newborn examination.

Pat Hoddinott *General practitioner*
St Stephen's Health Centre, London E3 5ED

Martin Underwood *Senior lecturer*
Department of General Practice and Primary Care, St Bartholomew's and the Royal London School of Medicine and Dentistry, London EC1M 6BQ

1 Davies J, Hey E, Reid W, Young G. Prospective regional study of planned home births. *BMJ* 1996;313:1302-6. (23 November.)
2 Northern Region Perinatal Mortality Survey Coordinating Group. Collaborative survey of perinatal loss in planned and unplanned home births. *BMJ* 1996; 313:1306-9. (23 November.)
3 Department of Health. *Changing childbirth: Report of the expert maternity group.* London: HMSO, 1993.
4 Hall DMB, ed. *Health for all children. Report of the third joint working party on child health surveillance.* Oxford: Oxford University Press, 1996.
5 General Medical Services Committee. *Maternity medical services legal advice.* London: GMSC, 1995.

A revival of home births would have to be led by community midwives

EDITOR—In England and Wales in the mid-1930s, when over two thirds of deliveries took place at home, the maternal mortality ratio was over 400 per 100 000 births. Many avoidable maternal deaths occurred, most during home deliveries or emergency admissions to hospital. The scandal of high maternal mortality became the driving force behind the policy to move childbirth from home to hospital.[1] By 1960 maternal mortality had fallen to 39 per 100 000 births; by the 1980s it had fallen to less than 10/100 000. The fall in maternal mortality (and perinatal mortality) occurred in parallel with the fall in home deliveries, and obstetricians, assuming that these events were connected, concluded that there was no longer any place for births at home.

Others have disagreed, and the Northern Region Perinatal Mortality Survey Coordinating Group suggests that at least a tenth of births could take place safely at home.[2] Who, then, is to provide intrapartum care for these mothers? The Home Birth Study Steering Group notes that many general practitioners today are unsupportive of home births.[3] This is not surprising. If, in the future, a tenth of births took place at home and if all general practitioners became supportive, general practitioners would probably be called to about a third of home deliveries. General practitioners would then, on average, attend less than one delivery a year—or 2.3 births a year if they attended every home delivery. At this level, if there is to be a revival of home births it must clearly

be in the hands of community midwives, as the Dutch system is.[4] General practitioners will not have the continuing experience to play an important part in intrapartum care.

Irvine Loudon *Medical historian*
The Mill House, Wantage OX12 9EH

1 Loudon I. *Death in childbirth*. Oxford, Clarendon Press, 1992.
2 Northern Region Perinatal Mortality Survey Coordinating Group. Collaborative survey of perinatal loss in planned and unplanned home births. *BMJ* 1996; 313:1306-9. (23 November.)
3 Home Birth Study Steering Group. Prospective regional study of planned home births. *BMJ* 1996;313:1302-6. (23 November.)
4 Weigers TA, Keirse MJNC, van der Zee J, Berghs GAH. Outcome of planned home and planned hospital births in low risk pregnancies: prospective study in midwifery practices in the Netherlands. *BMJ* 1996;313:1309-13. (23 November.)

Inability of community midwifery to cope with increase in home confinements is a blessing

EDITOR—The tacit encouragement of home confinements by the Northern Region Perinatal Mortality Survey Coordinating Group[1] not only is socially dangerous but ignores more recent national data on the relative safety of the place of birth.[2] The only analysis that can address the safety of home versus hospital is one that removes the confounding variables of obstetric outcome—that is, prematurity, low birth weight, antepartum death, and congenital abnormality. This is done in table 3 in the Northern region's paper but was also previously performed on a total national database based on the national confidential inquiry into stillbirths and deaths in infancy in 1993.[3] A similar analysis of intrapartum deaths of term infants for the West Midlands in 1993-5 has recently been completed (in house data). Table 1 summarises these three datasets.

It is interesting to note that although all papers quote similar risks of an intrapartum death of a term infant for a planned home delivery, the risk of a similar death in hospital in the Northern region is significantly greater than nationally (relative risk 2.2 (95% confidence interval 1.9 to 2.5), P = 0.000001) or in the West Midlands (2.42 (2.0 to 3.0), P = 0.00000l). Maybe the authors can explain this discrepancy, but it seems that pregnant women cannot yet take heart from the Northern region's figures. While the West Midlands figures are not dissimilar from the national estimates, the database is too small to show a significant difference between home and hospital. This underlies the importance of national inquiries in answering questions on uncommon outcomes.

But there is another concern. If the national data prove to be a more correct assessment of the risk of home confinements then a rise in the rate of home delivery from just under 2% in 1995 to 10% nationally, as suggested, would result in a 15% increase in intrapartum deaths of low risk term fetuses. Maybe safety is no longer the most important issue to some, but let us first be clear about the practice we are discussing. Recent national data suggest strongly that hospital is safer; those who wish to bury their heads in the sands of community care should beware that the sands are shifting. The inability of community midwifery services to cope with any substantial increase in home confinements is a blessing in disguise, not a deficiency needing correction.

Prakashbhan S Persad *Research fellow*
West Midlands Perinatal Audit, Solihull Hospital, Solihull B91 2JH

1 Northern Region Perinatal Mortality Survey Coordinating Group. Collaborative survey of perinatal loss in planned and unplanned home births. *BMJ* 1996; 313:1306-9. (23 November.)
2 Persad PS, Settatree RS. Place of birth and intrapartum-related perinatal mortality in the UK. *Prenat Neonat Med* 1996;1:259.
3 Confidential Inquiry into Stillbirths and Deaths in Infancy. *Annual report January to December 1993. Part 1*. London: Department of Health, 1995.

Author's reply

EDITOR—Prakashbhan S Persad finds different risks for those not booked for home birth because like is not being compared with like. We included all deaths at 0-27 days, the national study all deaths at 0-6 days, and Persad only intrapartum deaths at 0-6 days. Our study covered 14 years, during which mortality declined (fig 1). Deciding when death occurred can be difficult when no professional is present throughout labour, while abruption during early labour can be hard to differentiate from abruption precipitating labour. Such issues arose in 23% (7/31) of the cases notified to the national study from this region in 1993,[1] invalidating any comparison lacking standardised inclusion criteria.[1 2] We studied deaths among women booked for home birth wherever delivered; others merely studied those booked and delivered at home.

Table 1 Results of three studies of intrapartum deaths

	Northern region (1981-94)[1]	England and Wales (1993)[2*]	West Midlands (1993-5)*†
No of deaths at home (planned home delivery)	5/2689	9/5294	2/1286
Risk of death at home	1:538	1:588	1:643
All other deaths	642/520 280	379/671 448	106/208 201
Risk of all other deaths	1:810	1:1772	1:1964
Death at home *v* all other deaths:			
Relative risk	1.51	3.04	3.05
95% CI	0.6 to 3.6	1.6 to 5.9	0.8 to 12.4
P value	0.24	0.004	0.14

*Assuming that half of all home deliveries are planned. †In house data, 1996.

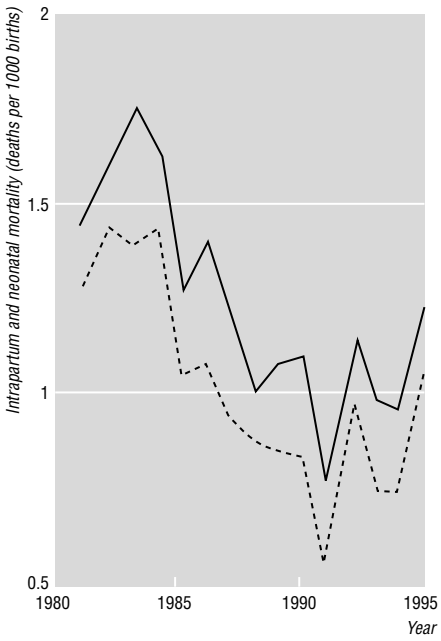

Fig 1 Intrapartum and neonatal mortality in babies that were not malformed of ≥2500 g in the former Northern region, 1981-95. Rate excluding late neonatal (7-27 day) deaths is shown by dotted line

It is also wrong to say that we ignored the national study (the confidential inquiry), even though it was incomplete, lacked back validation, and uses data still not open to independent scrutiny. Home birth became statistically more hazardous in this dataset only because some mothers "refused any intervention and were reluctant to be transferred"[3]; this was not a situation we encountered. Anyway, Persad ignores the data from other countries pointing to the relative safety of home birth. Our report gave no "tacit encouragement" to anything, merely reporting the facts as we found them.

Our intrapartum and neonatal mortality for 1984-95 in non-malformed babies of ≥2500 g was (non-significantly) lower among women booked for a home birth (1:2297 births) than for all other births (1:861 births), as expected for such a low risk group; whether it could have been even lower cannot be decided simply by comparing rates for groups at dissimilar risk. If these results are atypical we should ask why, rather than dismiss the findings as unrepresentative.

Persad stigmatises our report as "socially dangerous," but it is the few obstetricians who continue to ignore maternal autonomy who are behaving in a socially dangerous way. Such attitudes could increase the number of deliveries at which no doctor or midwife is present. Women will start to think that health professionals are behaving in a more balanced way when they give as much attention to the 98% of deaths associated with birth outside hospital that are not associated with planned home birth as they give to the 2% that are.

Edmund Hey *On behalf of the Northern Region Perinatal Mortality Survey Coordinating Group*
Maternity Survey Office, Newcastle upon Tyne NE2 4AA

1 Report on stillbirth and infant death in the former Northern region, 1993. Newcastle: Northern and Yorkshire Regional Health Authority, 1994,17-8.
2 *Confidential enquiry into stillbirths and deaths in infancy. Annual report 1993*. London: Department of Health, 1995.
3 Dowswell T, Thornton JG, Hewison J, Lilford RJL, Raisler J, Macfarlane A, *et al.* Should there be a trial of home versus hospital delivery in the United Kingdom? *BMJ* 1996;312:753-7.

Coffee drinking and risk of coronary heart disease

Cholesterol concentrations may have been within natural fluctuations

EDITOR—Rob Urgert and colleagues compared the effects of filtered and cafetière coffee on blood lipid concentrations and found that "After 24 weeks low density lipoprotein cholesterol concentrations were raised by 0.26 (SE 0.11) mmol/l, or 9% over baseline values relative to filtered coffee ($P = 0.03$)."[1] I am sceptical about the biological importance of differences with P values of this order; nor can we rule out the possibility that, had the experiment continued for longer, the plasma cholesterol concentration in the cafetière group might have returned to around the baseline value.

During the follow up the plasma cholesterol concentration rose to considerably above the baseline value (5.25 *v* 4.99 mmol/l) in the group who had previously drunk filtered coffee, although no statistical analyses are presented. The value of 5.25 mmol/l was higher than that in the cafetière group at the end of the treatment period (5.16 mmol/l), which the authors regarded as considerably raised. During follow up the cholesterol concentrations in the group that had previously consumed cafetière coffee fell below the baseline value (4.91 mmol/l) to 4.88 mmol/l. A reasonable interpretation is that the changes are within the natural fluctuations in blood cholesterol concentration over time. Plasma cholesterol concentration varies diurnally, seasonally, and under stress.[2] Average monthly differences may range from 8% to 20% in groups of people and up to 67% in individuals.[2]

The coffee used in this study was exceptionally strong. Participants consumed the equivalent of 10 or more average sized cups daily of a strength unlikely to be consumed in Britain. This study needs to be viewed alongside the results of several epidemiological studies showing that coffee drinking is associated with no significant risk of coronary heart disease[3 4] or even a lower risk than that among people who drank no coffee at all.[5]

M I Gurr *Visiting professor in human nutrition*
Vale View Cottage, Maypole, St Mary's, Isles of Scilly TR21 0NU

1 Urgert R, Meyboom S, Kuilman M, Rexwinkel H, Vissers MN, Klerk M, *et al.* Comparison of effect of cafetière and filtered coffee on serum concentrations of liver aminotransferases and lipids: a six month randomised controlled trial. *BMJ* 1996;313:1362-6. (30 November.)
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3 Department of Health. *Nutritional aspects of cardiovascular disease*. London: HMSO, 1994. (Report on health and social subjects 46.)
4 Willett W, Stampfer M, Manson J, Colditz GA, Rosner BA, Speizer FE, *et al.* Coffee consumption and coronary heart disease in women. *JAMA* 1996;275:458-62.
5 Brown CA, Bolton-Smith C, Woodward M, Tunstall-Pedoe H. Coffee and tea consumption and the prevalence of coronary heart disease in men and women: results from the Scottish heart health study. *J Epidemiol Community Health* 1993;47:171-5.

Authors' reply

EDITOR—M I Gurr asks whether the blood cholesterol concentrations in our subjects drinking cafetière coffee could have returned to the baseline value if treatment had lasted longer than six months. This is unlikely: the 6% increase that had persisted after half a year of drinking cafetière coffee is similar to that found in observational studies in which lifelong consumers of boiled coffee were compared with people who drank filtered coffee.[1] A permanent increase in blood cholesterol concentration of this magnitude will increase the risk of heart disease by 12% or more. Both the P value for the effect and the consistent cholesterol raising effect in all the experiments that have studied the responsible substance, cafestol,[2] make it improbable that the observed rise in blood cholesterol with cafetière coffee was due to chance.

In the follow up period cholesterol concentrations in the group who had consumed cafetière coffee fell below those in the group who had consumed filtered coffee. By comparing absolute values in the two groups at different time points Gurr argues that these changes are natural fluctuations over time. The only valid way to evaluate the results of a controlled trial, however, is to compare the changes from the baseline value in the treatment group with the concurrent changes in the control group. This will eliminate the effect of fluctuations—such as those caused by seasonality, which in a randomised trial will affect both groups to a similar extent—and gives the true effect of a treatment.

Although we agree with Gurr that our subjects used stronger coffee than is common in Britain, we do not see how this relates to Gurr's doubts about a link between coffee and heart disease. Gurr refers to studies in the United States and Scotland, where most people drink filtered or instant coffee. Absence of an effect of filtered or instant coffee on coronary risk is to be expected: these types of coffee do not contain cafestol[3] and thus do not affect the metabolism of cholesterol.[1] In contrast, a longitudinal study in a population with a high intake of boiled coffee did show a positive association between coffee and coronary mortality.[4] Again, this was to be expected: boiled coffee is rich in cafestol[3] and increases blood cholesterol concentration long term in lifelong consumers.[1] Our study shows that similar effects are to be expected with cafetière coffee.

Rob Urgert *Nutrition researcher*
Martijn B Katan *Professor*
Department of Human Nutrition, Wageningen Agricultural University, 6703 HD Wageningen, Netherlands

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Ratio of inhaled corticosteroid to bronchodilator as indicator of quality of asthma prescribing

Authors discuss a result that was not shown

EDITOR—The paper by Michael Shelley and colleagues on the ratio of inhaled corticosteroids to bronchodilators prescribed shows an innovation in research reporting—discussion of a result that has not been shown.[1] Having failed to confirm any association between this prescribing ratio and rates of admission to hospital for asthma within either a group of deprived practices or a group of more affluent practices, the authors then discuss the reasons for inconsistencies between these two non-associations and the role that deprivation may have.

No associations are visibly evident in their scatterplots of the data, and I suspect that other readers would also have had difficulty in deciding which of the plots related to the non-significant positive correlation (Spearman's $r = 0.038$, $P = 0.792$) and which to the negative correlation ($r_s = -0.218$, $P = 0.136$). No hypothesis of a difference between these two correlations was tested.

Nevertheless, I agree with the authors that the ratio of inhaled corticosteroids to bronchodilators prescribed may not be a good indicator of the quality of treatment of asthma. As with all ratios and percentages, it gives no indication of the absolute quantities concerned. Small ratios could derive from good prescribing of inhaled steroids for asthma and overprescribing of bronchodilators for asthma, chronic obstructive pulmonary disease, or chronic bronchitis; alternatively, small ratios could derive from reasonable prescribing of bronchodilators with a deficiency in prescribing of inhaled steroids to asthmatic patients. The quality of prescribing in asthma might possibly be indicated by the quantity of inhaled steroids relative to the number of asthmatic patients. There is no evidence, however, that the quantity of bronchodilators prescribed is a good surrogate measure for the number of patients with asthma in a practice, especially as asthma is far less strongly related to age than many of the other respiratory conditions for which bronchodilators are additionally prescribed.[2]

There are no absolute measures of quality in any aspect of medical care, as quality

means different things depending on your viewpoint. Is there any evidence that high rates of admission to hospital for asthma indicate poorer treatment of asthma in primary care? Other things being equal, perhaps there is, but the diverse circumstances of different practice catchment populations probably exclude this and many other simple putative measures for comparing quality at individual practice level.

Sarah J Roberts *Lecturer in medical statistics*
Wolfson Unit of Clinical Pharmacology, University of Newcastle, Newcastle upon Tyne NE2 4HH

1 Shelley M, Croft P, Chapman S, Pantin C. Is the ratio of inhaled corticosteroid to bronchodilator a good indicator of the quality of asthma prescribing? Cross sectional study linking prescribing data to data on admission. *BMJ* 1996;313:1124-6. (2 November.)
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Prescribing data need to be available by age

EDITOR—Michael Shelley and colleagues found no relation between the ratio of inhaled corticosteroid to bronchodilator prescribed and admissions to hospital with asthma.[1] An additional problem of using prescribing analysis and cost (PACT) data that the authors do not mention is that prescriptions are not recorded by age. Some of the prescriptions in their study would have been for children. Prescribing analysis and cost data were used in an audit of admissions with asthma among children in west Devon, where a single hospital provider admits children.

Hospital admissions over six years were identified from the patient administration system, and practices' populations of children were identified from the child health computer. Townsend deprivation scores were calculated from each child's postcode.[2] Prescribing analysis and cost data on the use of sodium cromoglycate by practice were compared with practice admission rates; sodium cromoglycate was chosen instead of inhaled corticosteroids because it is used widely to treat childhood asthma. Hospital admission rates by practice varied between 0.9 and 17.2 per 1000 children a year. There was no significant association between the admission rate and the size of the practice, number of prescriptions of sodium cromoglycate per child per year, or number of admissions for all reasons over the same period. There was a significant positive association between the rate of hospital admissions with asthma and the Townsend score for each of the 52 wards ($r = 0.50$, $P = 0.0002$). This association was even stronger ($r = 0.65$) for the 20 urban wards, 10 of which had Townsend scores > 5, but it was not significant for the 32 rural wards with lower scores. There was also a significant positive correlation between the number of admissions for asthma per child and the Townsend score ($r = 0.37$, $P = 0.007$). The association between social deprivation and rate of admission for asthma did not explain the observed differences in admission rate among practices.

This audit confirms a positive association between social deprivation and the rate of admission for asthma in children.[3] Most children admitted to hospital with asthma are aged under 5 years. In this age group other factors such as the difficulty in achieving good inhaler technique and in assessing the severity of illness are important in achieving control. The reasons why hospital admission rates are higher in deprived areas need to be explored further; poor compliance with treatment, lack of understanding of the management of asthma, and inappropriate use of health services may prove important. The relation between treatment of asthma in children in primary care and hospital admissions cannot be examined unless prescribing data are available by age.

J H Baumer *Consultant paediatrician*
Department of Child Health, Derriford Hospital, Plymouth PL6 8DH

1 Shelley M, Croft P, Chapman S, Pantin C. Is the ratio of inhaled corticosteroid to bronchodilator a good indicator of the quality of asthma prescribing? Cross sectional study linking prescribing data to data on admissions. *BMJ* 1996;313:1124-6. (2 November.)
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3 Watson JP, Cowen P, Lewis RA. The relationship between asthma admission rates, routes of admission, and socioeconomic deprivation. *Eur Respir J* 1996;9:2087-93.

More adequate information systems are needed

EDITOR—We would like to discuss several points that may raise doubts about the validity of the study by Michael Shelley and colleagues.[1] They used rates of hospital admission as a main outcome measure. We hypothesise that asthmatic patients who do not comply with treatment and whose asthma is poorly controlled are more likely to be admitted and that their prescribing patterns will be more influenced by the opinions of hospital doctors as a result of both discharge summaries and subsequent outpatient correspondence.

The authors raise the effect of readmissions to hospital as a possible source of aberration. A further effect is the use of finished consultant episodes rather than deaths and discharges as a measure of activity. A single admission or hospital transfer may generate more than one finished consultant episode—for example, in the event of severe acute asthma when a patient may require ventilation in intensive care. If, after stabilisation, the patient was transferred to a general medical ward under the care of a different consultant these events would generate at least two finished consultant episodes.

In addition, the study attempts to examine the issue of deprivation. Ill health is well recognised to be related to material disadvantage.[2 3] Possibly the pattern of admissions with respect to asthma may be a function of that seen elsewhere in the general population. This is further complicated by the observation that general practices are often heterogeneous in terms of the profile of deprivation of the areas that they cover. Asthma prescribing varies at the level of the individual general practitioner and not the practice; this is particularly important in large practices. The demography of individual general practices will also vary quite widely. Standardisation of the data presented in Shelley and colleagues' figure 1 by sex and, more importantly, age may have a notable effect.

Finally, we question the use of the word linking in the title of their paper. This implies that these data had undergone some form of record linkage or probability matching.[4] It would be technically possible to link prescribing analysis and cost (PACT) data to routine inpatient data by using probability matching algorithms since prescriptions contain information pertaining to the identity of patients, although this information is not routinely recorded.

The use of these routine sources of data to answer important questions such as that raised here should be promoted, mainly because these sources of data are readily available. The use of more adequate information systems, with a common hospital identification number throughout the NHS would have aided the authors in their investigation.

Craig J Currie *Research officer*
Mark Evans *Research registrar*
Christopher L Morgan *Research officer*
Department of Medicine, University Hospital of Wales, Cardiff CF4 4XW

1 Shelley M, Croft P, Chapman S, Pantin C. Is the ratio of inhaled corticosteroid to bronchodilator a good indicator of the quality of asthma prescribing? Cross sectional study linking prescribing data to data on admissions. *BMJ* 1996;313:1124-6. (2 November.)
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Outcome measures need to reflect morbidity and quality of care

EDITOR—Michael Shelley and colleagues found no significant correlation between the ratio of prophylaxis to bronchodilators and rates of admission for asthma in West Midlands.[1] This is a useful contribution to the debate about markers of quality of prescribing but contrasts with our findings in east London.[2]

Several aspects of their study deserve comment. Firstly, they examined admission rates for all ages. The diagnosis of asthma is least secure at the extremes of age. We wonder whether restricting their analysis to ages 5-64 might yield a relation between admission rates and prescribing.

Secondly, they included readmissions but do not say what proportion readmissions contributed to the total admission rate. In east London in 1991-4 readmissions accounted for 40% of all admissions yet constituted only 19% of patients admitted. It is unclear whether similar factors relate to both admission and readmission. Patients' preferences about the availability of services such as nebulisation[3] or perceptions of

severity may mean that factors relating to readmission and admission differ.

Thirdly, the allocation of the Townsend score of the electoral ward in which the practice was located is an approximation: some patients who are admitted live in wards other than that of their registered practice. A more accurate method is proportional allocation of ward data based on patients' postcodes.[4] Ultimately, the most accurate way of linking patient demography to admission rate will be to gather data prospectively on individual admissions.

Fourthly, daily defined doses may be a more accurate measure on which to base prescribing ratios, but it would have been helpful to know the correlation between ratios based on daily defined doses and items of data presented by Shelley and colleagues.

Any ratio of prophylaxis to bronchodilators prescribed is a crude representation of how practices prescribe for asthma. While higher levels of prescribing of prophylaxis may result in better control of asthma, other elements of prescribing may relate more closely to admission rates. Meta-analysis shows a strong link between use of oral steroids in exacerbations and reduced likelihood of admissions.[5]

Prescribing in asthma may ultimately be marginal in explaining variations in admission rates. Our multiple regression analysis of doctor, general practice, prescribing, and demographic factors suggests that, at least for east London, partnership size is the factor that relates most strongly to admission rates (C Griffiths et al, annual scientific meeting of the Association of University Departments of General Practice, 1996). Clearly, outcome measures need to be developed that accurately reflect morbidity and quality of care. Prescribing may be only one aspect of these.

Chris Griffiths *Senior lecturer*
Patricia Sturdy *Research officer*
Jeanette Naish *Senior lecturer*
Gene Feder *Senior lecturer*
Department of General Practice and Primary Care, St Bartholomew's and the Royal London School of Medicine and Dentistry, London EC1M 6BQ
Rumana Omar *Lecturer*
Department of Medical Statistics, Royal Postgraduate Medical School, London W12 0NN
Susan Dolan *Research analyst*
General Practice and Primary Health Care, Imperial College School of Medicine at St Mary's, London W2 1PG
Filomena Pereira *Lecturer*
Department of Epidemiology and Medical Statistics, Queen Mary and Westfield College, London

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Authors' reply

EDITOR—Sarah J Roberts suggests that non-significant findings are not worthy of discussion and considers that ratios are poor measures of prescribing. The ratio of inhaled corticosteroid to bronchodilator is, however, widely used in clinical practice and by medical and pharmaceutical advisers as one measure of the quality of prescribing for asthma.[1] It is through empirical research such as ours and that of Griffiths *et al*[2] that the use of such indicators can be critically explored.

The use of prescribing analysis and cost (PACT) data as a measure of prescribing by general practitioners is not ideal because these data are not linked to individual patient characteristics. Factors such as age or morbidity are, as stated by J H Baumer, Craig J Currie and colleagues, and Chris Griffiths and colleagues, important influences on such data. In our paper, for example, we discussed the severity of disease and chronic obstructive pulmonary disease in older patients as possible explanations of the contrasting associations between prescribing analysis and cost data and admissions for asthma in deprived and affluent areas.

Baumer and Griffiths and colleagues provide additional evidence that socioeconomic circumstances and differences between practices are strong predictors of admissions for asthma. In children Strachan *et al* found differences in morbidity from asthma across the social classes which were not paralleled by variations in treatment.[3] The extent to which access to efficiently delivered care of asthma and appropriate prescribing can overcome the adverse effects of physical and social deprivation, however, remains to be determined.

Admission to hospital was used as our outcome measure because it is the only record of morbidity from asthma available from all general practices. We agree that the admission rate is a crude measure of outcome. We used finished consultant episodes as opposed to actual admissions. Currie and colleagues point out that a single admission may generate more than one finished consultant episode. We considered this effect to be small (700 admissions accounted for the 764 finished consultant episodes in our study). Similar results were observed whether finished consultant episodes or admissions were used. Fourteen per cent of admissions were readmissions of fewer than 11% of the patients.

We agree that existing prescribing databases need to expand links with patient demographics, diagnosis, and morbidity. This will allow the interrelations between the severity of symptoms, social inequality, and access to optimal care in asthma to be explored further. We have now completed such a study with an analysis of prescribing in asthma and morbidity at the level of individual patients.

Michael Shelley *Research pharmacist*
Peter Croft *Professor of epidemiology*
Charles Pantin *Senior lecturer*
Industrial and Community Health Research Centre, School of Postgraduate Medicine, Keele University, North Staffordshire Medical Institute, Stoke on Trent ST4 7NY
Stephen Chapman *Director of prescribing analysis*
Department of Medicines Management, Keele University, Keele, Staffordshire ST5 5BG

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Increasing empathy between medical students and nurses

EDITOR—As senior medical students we were most interested to read the recent letter from Siklos and Kennedy[1] discussing the relationship between doctors and nursing staff and the need for a two day nursing placement for medical students, and also J Hughes' letter of a similar nature.[2]

The authors are keen to extol the virtues of the two day nursing placement which medical undergraduates undergo at Cambridge. They, and indeed your readers, may be interested to know that such placements are not unique to Addenbrooke's. For example, at St Mary's and its associated hospitals an entire week is devoted to nursing duties at the start of the clinical course. A number of objectives and requirements must be signed off for each student in the hope of increasing future doctors' understanding of the role and importance of the nursing staff.

From our experience on clinical firms and house officer assistantships, nurses are often regarded as the bedrock "holding the ward together"; indeed, one of the golden rules passed on to newly qualified house officers is to get on the good side of the nursing staff. An additional, and in our view, important consideration is that a significant proportion (perhaps 10-15%) of medical students carry out auxiliary nursing duties where regulations allow. While augmenting otherwise overstretched grants and loans, this practice is perhaps even more likely to increase empathy between medical students and nurses.

These approaches can only contribute in a positive manner to a more comprehensive and sympathetic understanding of the crucial services provided by nursing staff and therefore pave the way to continued good working relationships within the close-knit hospital community—the goal being optimal patient care.

Hiten G Sheth *Final year medical student*
Rajeev Mallipedi *Final year medical student*
St Mary's Hospital, London W2

1 Siklos P, Kennedy R. Medical students in Cambridge do two nursing shifts. *BMJ* 1997;314:306. (25 January.)
2 Hughes J. Nurses need to accept more responsibility, and doctors need better training. *BMJ* 1997;314:306. (25 January.)