referring complex cases to specialist colleagues. In mixed systems, paediatricians work in larger population centres, and general practitioners provide care in small communities. Which is best? Evidence is scanty. In Europe, a system of primary care paediatricians was claimed to be associated with better health indicators than one based on general practitioners, when other variables were controlled.²⁻⁸ The United Kingdom performs as well as other European Union states in treating acute leukaemia and lymphoma, but relatively poorly for solid tumours, which present more insidiously,¹⁰ a finding that might be due to delayed referral by primary care services in the United Kingdom. International comparisons show, however, that primary care in the United Kingdom may be more cost effective than systems based on specialists.²

Tomorrow's parents and young people will expect their doctor to have confirmed competences in acute and non-urgent children's care, particularly psychological disorders and chronic disease. But the new contract does not encourage general practitioners to undertake formal training in these areas. It offers additional remuneration based on a points system for high quality care programmes but child health surveillance (a term made obsolete by the national service framework) gets just six points. In contrast, cervical screening can get 22 points, mental health work 41 points, diabetes 99, and heart disease 121. This structure may encourage general practitioners to focus on and develop special interests in adult health and chronic disease.

General practice is at a crossroads, and we need to contemplate the implications of either nurturing or abandoning the concept of the whole family doctor.¹⁰ To maintain their place as the main providers of health care for children and young people, general practitioners will need appropriate training and remuneration

for providing a practice based quality child health service for the 21st century and opportunities to develop special interests in various aspects of child and adolescent health.¹¹ The alternative is that children's health care will increasingly be offered outside general practice by a range of other disciplines and providers,¹² supported by a new generation of general paediatricians for whom traditional barriers between hospital and community will seem irrelevant.¹⁵

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Ethics review of research and audit

Journals should not abdicate their responsibility

Education and debate
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What is the difference between audit and research? This may be an impossible question to answer although it hasn't stopped people trying. The distinction has important consequences, as Derick Wade points out in this issue, one of which is that many ethics committees exclude audit studies from their remit (p 468).¹ Responsibility for classification of a study as research or audit currently rests primarily with the investigator. A question that we are asked frequently is whether or not approval from an ethics committee is required for audit. A second question is whether or not journals consider studies that do not have approval from an ethics committee.

Researchers understand why ethical approval is required for research. Many investigators also understand that seeking approval from an ethics committee has become a burdensome bureaucracy. In these pages, we spelt out the difficulties

researchers—be they devotees of research or dabblers in it—face in winning ethical approval for their study.²⁻⁴ Early experience indicates that this onerous process is suffocating research, particularly smaller studies.⁵ Some readers might welcome this development—the fewer meaningless and duplicated studies the better—but others argue that there is much to learn from precisely the kind of work that their colleagues are giving up on.

To help think through this ethical conundrum, audit might be better viewed as a subset of research rather than a notch down the evolutionary ladder. In terms of deciding on whether or not a study requires ethics approval it is better to ignore any arbitrary label, such as, say, audit or research that might become attached to the work, and consider carefully the nature of the study and its implications. With this in mind, Wade clearly outlines a method of considering whether or not a study warrants approval from an ethics

committee and argues that our current definitions of audit and research fail to consider the moral issues.

Journals, he suggests, are abdicating their responsibility if they assume that audit does not require approval from an ethics committee. Secondly, journals should not automatically defer to ethics committees—or the word of authors—and must have their own mechanisms for deciding on the ethical merits of research. In one of three commentaries, John Alexander, chair of a regional ethics committee, worries that “placing ethical responsibility with journals is dangerous.”^{7,8} Indeed it would be if the sole responsibility was transferred to journals. But Wade is proposing greater vigilance and public responsibility from journal editors and not hypothesizing that journals could ever be an alternative to ethics committees.

These issues have been extensively discussed at the *BMJ*'s ethics committee and at internal meetings. Our policy, which you will find on our website, http://bmj.bmjournals.com/advice/editorial_policies.shtml has been to judge the ethics of a study on its merits and disregard arbitrary distinctions between audit and research. If we are concerned, we seek clarification from the authors and possibly their ethics committee. We have, at times, asked authors to go back and seek retrospective approval from their ethics committee. We do not accept the decision of the local or regional ethics committee without question, and if necessary we will query the decision with that ethics committee. Our own ethics committee has an important role in guiding us.

Some readers—and journal editors—may be surprised at the vigour with which we pursue studies that

we are concerned about. They shouldn't be. The *BMJ* has been a central player in the formation of the Committee on Publication Ethics (COPE), whose new code places a responsibility on journal editors to investigate matters that worry them rather than simply rejecting a research paper because it would be easier to do so.⁹ Although correspondence with authors, ethics committees, university departments, and hospitals can be a painstaking and thankless battle with bureaucracy—just like seeking ethics committee approval—we believe that editors have a duty to take on issues of unethical audit or research. Our motivation is not to seek punishment for the authors but to prevent future unethical clinical practice and to protect patients.

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Mortality from sickle cell disease in Africa

Interventions used to reduce mortality in non-malarial areas may be inappropriate

After the first description of sickle cell disease in a Grenadian dental student in Chicago in 1910, subsequent reports indicated that the disease was confined to people of African origin. Over the next 40 years, the clinical features were recorded in Americans, but it was not until the late 1940s that reports began to appear from Africa itself. These documented the high prevalence of the sickle cell trait throughout equatorial Africa and its geographical coincidence with the distribution of *Plasmodium falciparum* malaria. Studies from west, east, and central Africa showed that individuals with the sickle cell trait had a relative protection against malaria during a critical period of early childhood. This was believed to offset the loss of sickle cell genes from the high mortality of homozygotes, illustrating the concept of balanced polymorphism. Although the sickle cell trait may have a survival advantage in malarial areas, the occurrence of malaria in homozygous sickle cell (SS disease) is almost certainly a major determinant of morbidity and mortality. The interaction of malaria with SS disease is likely to change many of the

features of the disease and casts serious doubt on the relevance of interventions developed in non-malarial areas.

This may be illustrated by two interventions shown to reduce mortality in non-malarial areas. The early loss of splenic function in patients with SS disease renders them prone to overwhelming septicaemia especially in early childhood, 85-90% of which is due to *Streptococcus pneumoniae*.¹ Pneumococcal prophylaxis reduces morbidity and mortality²⁻³ and is now routine in the management of severe sickle cell syndromes. There is now pressure to implement similar prophylaxis for African patients, but what do the data show? Early reports from the then Belgian Congo and from Nigerian adults noted a high prevalence of *S pneumoniae*.⁴⁻⁵ However, more recent studies of children with septicaemic sickle cell disease in Nigeria⁶⁻⁸ and Uganda (Monica Etima, personal communication, 2004) have found that less than 10% of septicaemias were due to this organism and that septicaemia due to *Staphylococci*, *Escherichia coli*, *Salmonella*, and *Klebsiella* predominated.

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