Birdsell, an economist at the centre, called for more research into "why programmes succeed when they do" at the Global Forum On Health Research in December.

Hardest of all is to recognise the lessons learnt from success or failure, see their wider potential, and successfully adapt them to other healthcare settings. Among the many factors that influence any project, sound management, good leadership, and active community participation are likely to be important. Brazil, for example, has succeeded in reaching and sustaining very high childhood immunisation rates against nine diseases. The last indigenous case of measles was reported in 2000.[3] Public support for vaccination campaigns has been strong; temporary shortages of vaccines in 1997 resulted in public protests. This is in sharp contrast to the situation in several developed countries, where intense media coverage of possible side effects of vaccines and failure to mobilise public support have contributed to falls in immunisation rates.

The reluctance of health professionals in developed countries to abandon established treatments in favour of simpler low cost options may be one of the many barriers to adopting practices pioneered in less developed countries. Kangaroo care—keeping very low birthweight infants upright on their mother's chest in direct, skin to skin contact, marsupial style—may be an example. It was developed more than 20 years ago in Colombia in response to overcrowding and lack of resources in special care baby units. Further evidence is needed to confirm promising results of its effect on reducing infant mortality, but it seems to offer additional benefits to mothers.[4]

In November the *BMJ* will publish a theme issue on "learning from developing countries." Its aim is to flag up innovative, cost effective health initiatives and interventions in developing countries, which have or show clear promise of having useful lessons for health professionals, policy makers, and researchers in the developed world. It also hopes to draw attention to initiatives that may promote learning between developing countries and discuss what we can learn from interventions that have failed.

Original papers for this issue should reach us by the end of May. Authors should discuss the potential of their work for wider learning and adaptation, and suggest what further research is needed to explore this. We also welcome submissions for other sections in this issue. In an increasingly globalised world we have much to learn from each other.

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Advice to contributors is provided on bmj.com. Submissions should be made to http://submit.bmj.com/ and the covering letter should make it clear that the article is intended for the "Learning from developing countries" theme issue.

The guest editors for this theme issue are Rashad Massoud, director, Quality and Performance Institute, University Research Co, LLC/Center for Human Services, 7200 Wisconsin Avenue, Suite 600, Bethseda, MD 20814, USA; Cesar G Victora, professor of epidemiology, Federal University of Pelotas, CP 464-96001-970 Pelotas, RS, Brazil; James Tumwine, associate professor of paediatrics and president of FAME (Forum of African Medical Editors), Makere University, Kampala, Uganda; and Zulfiqar Bhutta, Husein Lalji professor of paediatrics and child health, The Aga Khan University, Karachi 74800, Pakistan.

Implementing the European clinical trials directive

Discussions continue in the European Commission and the United Kingdom

Letters p 286

The European Union's clinical trials directive must be implemented in United Kingdom law by May 2004.[1] It is intended to simplify and harmonise the regulation of clinical trials across the European Union, thereby facilitating the internal market in medicinal products while protecting participants and public health. Yet some have expressed concern that it will actually impede and inhibit publicly funded clinical trials, a sector of research in which the United Kingdom has always been strong.[2–4] What are the contentious issues, and where do matters now stand?

The Medicines and Healthcare products Regulatory Agency (MHRA) is the regulatory body responsible for drafting the UK legislation to be laid before parliament early in 2004. In preparation for this the agency consulted widely in February 2003 and provided advice and a helpline via its website (http://medicines.mhra.gov.uk/ourwork/licensingmeds/types/clintrialdir.htm).[5] The main concerns elicited were around the role and responsibilities of the sponsor of the trial, the delay and cost imposed by additional bureaucracy, and new requirements for good clinical practice, pharmacovigilance, and good manufacturing practice standards for investigational medicinal products.[6 7] A joint project has been set up by the Department of Health and the Medical Research Council to help trialists and the Medicines and Healthcare products Regulatory Agency by documenting current best practice in these areas and to provide advice on systems and approaches that will comply with the law while minimising unnecessary burdens.[8]

The directive defines a sponsor as "an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial" and sets out the legal obligations of the sponsor. The model is clearly based on the industry context, where the company taking an innovative compound through its development programme is self evidently the sponsor. Non-commercial

BMJ 2004;328:240–1

trials have usually operated on a different basis. The principal investigator, his or her employer (often a university), a funding body (which might be a charity, the Medical Research Council, or part of the NHS research and development programme) and a clinical host organisation (typically one or more NHS trusts) collectively take responsibility for various aspects of research governance. However the UK regulations are framed, there will need to be more explicit allocation of responsibilities between partner organisations. This is right in principle both for the protection of patients and the assurance of scientific rigour, though the details of how this is best achieved continue to be debated. Some concern has been expressed at the penalties to which the sponsor would be liable. These should be seen in the context of liabilities which already exist. To use an analogy, the introduction of compulsory testing of motor vehicles created a new penalty for driving a vehicle without a valid test certificate—but it reduced the larger risks, financial and physical, of driving on bald tyres.

For good clinical practice and pharmacovigilance, the appropriate level of supervision would be expected to differ for a drug undergoing first use in humans and a long marketed drug now being tested in a new indication. Such proportionality would answer many of the concerns raised about needless bureaucracy. Neither the directive on good clinical practice nor the guidance on pharmacovigilance has yet been agreed within the European Union. This has delayed the drafting of UK regulations, which will be influenced by the level of detail specified in the directive. The United Kingdom has a treaty obligation to transcribe the directive into national legislation, and thereafter it will be the task of the Medicines and Healthcare products Regulatory Agency to act as the regulatory body. Much will therefore depend on the degree of discretion permitted by the directive with regard to good clinical practice and pharmacovigilance.

If monitoring is made proportionate to risk, no logical basis exists for a different standard of supervision in commercial and non-commercial clinical trials. The directive makes no distinction between the two. More research staff with better professional training and support may be needed in some publicly funded research in order to safeguard quality and safety. The case for extra funds is best supported by an objective examination of the infrastructure needed to attain the required standard.

Research is an essential component of a high quality healthcare system, not an optional extra. Publicly funded clinical trials in the United Kingdom have made a large contribution to improved care. A wider debate is beginning on how clinical trials can be fostered in the NHS, and how therapeutic innovation can be encouraged and the research potential of the NHS better used.[9 10] All research partners (investigators, universities, funders, and NHS organisations) have a shared interest in achieving high standards of research governance, but their procedures for doing so need to be better coordinated. Compliance with the directive will challenge us to review many details of current practice. Can we find ways of streamlining the initiation of trials without compromising patient safety?

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Competing interests: KW was director of the NHS Health Technology Assessment Programme and chairman of the MRC/DH joint project before joining MHRA in January 2004.

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Access to antiretroviral treatment in Africa

New resources and sustainable health systems are needed

Education and debate p 280; *Papers* p 249

The demand for people living with HIV and AIDS in Africa to access treatment cannot be ignored. At the same time the challenges to meeting this demand are many. They include the shortfalls in health services and lack of knowledge about treatment, making decisions about newer regimens, and the risk of resistance to antiretrovirals highlighted in the paper by Stevens et al (p 280).[1 2] The challenges also include ensuring uninterrupted drug supplies, laboratory capacities for CD4 monitoring, accessible voluntary counselling and testing, trained healthcare workers, and effective monitoring of resistance to antiretroviral drugs.[3] A series of papers produced in 2003 through the southern African regional network on equity in health raised further concerns about measures to ensure fairness in the rationing of scarce treatment resources and the diversion of scarce resources from strained public health services into vertical treatment programmes.[4–8]

The reasons for these challenges are not a mystery. They stem from the chronic under-resourcing of health systems, the underdevelopment of strategic

BMJ 2004;328:241–2