have tried to establish a dose-response effect have shown varying results. In trials the daily dose has ranged from two to 16 capsules of 500 mg. One capsule contains about 320 mg linoleic acid, 40 mg γ linolenic acid, and 10 IU of vitamin E. In the prescribing information a dose of three to six capsules twice daily is recommended. The clinical response is said to occur after three to four months and to last for several months.

Most trials have used placebo capsules containing paraffin and matching the capsules of evening primrose oil by colour and shape.¹³ The taste is different, but the capsules should be swallowed unbroken. In doses of 12 capsules daily the amount of vitamin E is a megadose (10 times the recommended daily allowance). Although there are valid arguments for using an inert placebo, one containing linoleic acid and vitamin E would make it possible to isolate the effect of linolenic acid.

The conclusion that I draw from the published research is that evening primrose oil has not been proved to be efficacious in rigorous clinical trials. Many of the trials to date have been crossover studies in small numbers of patients. Publication bias cannot be ruled out (practically all trials have been sponsored by the same company), and for most conditions for which evidence exists from several trials both positive and negative outcomes have been reported. Questions remain about the dose and duration of the treatment, and evening primrose oil should be compared with and shown to be more effective than linoleic acid and vitamin E. Nevertheless, evening primrose oil is an interesting substance, and for some indications it is a promising treatment—especially for diabetic neuropathy and atopic dermatitis, but also for rheumatoid arthritis and the

premenstrual syndrome. Further rigorous trials of both evening primrose oil and γ linolenic acid are warranted.

JOS KLEIJNEN
Clinical epidemiologist

Academic Medical Center,
University of Amsterdam,
Department of Clinical Epidemiology and Biostatistics,
PO Box 22700,
NL-1100 DE Amsterdam,
Netherlands

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Trial design in developing countries

The results of studies must be relevant to the populations in which they are carried out

Picture an impoverished region in sub-Saharan Africa where health services are virtually non-existent. A donor funds a group of scientists to test whether regular administration of a prophylactic drug or a micronutrient improves child health. The researchers build a research station, and staff deliver the intervention and record illness and death in the study population. After three years the results are published, the intervention is declared effective, and the scientists move on.

Yet back at the study site there are still no health services and micronutrients are still not being delivered. Has the research benefited the participants of the study? Should researchers be allowed to spend money and intervene in people's lives without helping to develop services to deliver the intervention being tested? Should intervention trials always be directly relevant to the needs and services of the area where the work is conducted? The European Commission is encouraging researchers to consider methods that ensure trials are useful to health managers' decision making as well as being scientifically valid (P Garner *et al*, European Commission meeting on methodology and relevance of field based intervention trials, Barcelona, June 1994).

Researchers face a dilemma. Reliable evidence for the effectiveness of interventions helps to ensure the wise use of scarce resources. Populations chosen for a

randomised controlled trial of an intervention in primary care are often poor, with high morbidity and mortality. Usually the health services in such areas are patchy and of poor quality and cannot be relied on either to deliver the intervention or to monitor the effect. In the pursuit of a scientifically valid study the researcher sets up an independent delivery system or adds to existing services in a way that distorts them. For similar reasons morbidity or mortality will be measured in systems separate from existing services.

Though all these aspects of the research design will maximise the chance of detecting a positive effect, it is unclear whether the results are useful to regional or national health managers. To begin with a large research project is likely to have a profound effect on a community, especially in deprived areas with few services. The effect of an intervention, therefore, may never be replicable in practice because the compliance of providers will not be the same. In addition the area being studied may simply not have the resources, skill, or organisational capacity to provide the intervention under test.

Problems in generalising research results are not unique to developing countries.¹ But by using resources that are not locally available research teams lose the opportunity to invest in existing health services. Could the money and skills devoted to these parallel systems be a stimulus to

improve health service functioning and morale? This could improve existing systems of care, encourage and support those delivering services, and maximise the chance of local and national ownership. But there is a risk of overloading already overworked staff. Conducting large randomised trials with a few relevant outcome measures may be the best way of improving local services. Health workers, by being part of the research process, would be able to see the value of the work.

Everyone agrees that it is important to establish that a new intervention has a potentially beneficial effect. But how quickly should researchers then move to implement it through existing services? Researchers and health service providers should be ready to contribute to the debate.

Contributors to this debate should contact Dr Marc De Bruycker, European Commission Directorate General XII,

Scientific Co-operation with Developing Countries—Area Health, Rue de la Loi, 200-B-1049 Brussels.

PAUL GARNER
Senior lecturer

Liverpool School of Tropical Medicine,
Liverpool L3 5QA

TESSA TAN TORRES
Lecturer

University of the Philippines,
Manila

PEDRO ALONSO
Head

Unidad de Epidemiologica,
Hospital Clinic i Provincial,
Barcelona

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Who's psychopathic now?

A recent report has few new solutions and calls for more research

The historical development of the concept of psychopathy reflects repeated attempts to define and explain an "elusive category" of person,¹ who does not suffer from mental illness yet differs fundamentally from other people because of an innate inability to exhibit normal social adjustment, a tendency to exhibit disorders of conduct and self control, and defects in personality development. Such people have consistently been regarded as constituting a specific and more or less identifiable group who justify definition, understanding, and treatment. The underlying aetiology has moved from Pinel's "manie sans delire" by way of moral insanity and born delinquency to "psychopathy," which embraced all non-psychotic mental illnesses (when it was coined early this century).

The present use of the term psychopath owes much to the influence of Sir David Henderson² and the Royal Commission on the Law Relating to Mental Illness and Mental Deficiency 1954-57,³ which led to the inclusion of psychopathic disorder in the Mental Health Act 1959 and its confirmation with important qualification in the act of 1983. Dissatisfaction with the concept of psychopathy is evident in the reports and debates that preceded the eventual decision to continue to sustain this category of mental disorder throughout the past decade. Various alternatives have been proposed and rejected, and the category continues to survive.

A recent report is the latest attempt to address this confusing topic.⁴ It considers the services needed for people with personality problems, the most effective methods of management and treatment, and the need for research and legislative change. The report is a realistic and pragmatic attempt to reduce the confusion and scepticism about this group of people whom many psychiatrists finally reject or feel unable to treat. It produces no simple answers and

recognises that treatment has failed to progress since the Butler report of 1975 last officially reviewed the subject.⁵ Some people may be disappointed that the report has not grasped the nettle and finally declared psychopaths to be a social and not a medical problem requiring the sympathy, empathy, and understanding of medically based services.

Instead, this report's recommendations include improved methods of categorisation, the promotion of research by government departments into the evaluation of a wide range of treatments and methods of management, more imaginative use of the Mental Health Act for assessment, a greater number of specialised units in hospitals and prisons, and the removal of the term psychopathic disorder from the act and its replacement by "personality disorder." As ever, the report's recommendations require funding and government support as part of a comprehensive programme integrated with other measures for mentally disordered offenders. Comments are requested by 30 November, and this provides the opportunity to urge the government to support the work to find solutions. Without support, and when difficult and painful choices are necessary in prioritising treatment, this group of patients is likely to be among the first to lose out.

ROBERT BLUGLASS
Professor of forensic psychiatry

Reaside Clinic,
Birmingham B45 9BE

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