

**South London & Maudsley NHS Trust and
Institute of Psychiatry, King's College London (KCL)**

Response to Cooksey Consultation

Funding Research on the Development and Evaluation of Innovative Therapies

As a supplement to the main KCL submission with its associated NHS Trusts to the Cooksey consultation, this paper addresses the need to establish an effective system for the allocation of the excess treatment costs necessary to allow the scientific investigation of innovative therapeutic interventions to take place. This response has been prepared by senior clinical academics representing core mental health disciplines with internationally recognised expertise in developing new treatments for psychiatric conditions, including psychological therapies for anxiety disorders, bipolar disorder, schizophrenia, obsessive-compulsive disorder, eating disorders, psychosomatic problems, and conduct problems in childhood – and in evaluating these treatments in large-scale multi-site randomised controlled trials with funding from sources including the Medical Research Council, the Wellcome Trust and other NHS recognized medical charities, and the Department of Health.

1. Over the last 25 years, the UK has been a world leader in the development of new and effective treatments for mental illness, including innovatory psychological and social therapies. Many of these psychological treatments, for example, are now recommended as treatments of choice by review bodies such as NICE, to be used either in conjunction with pharmacological treatments or for many conditions as the preferred treatment on grounds of effectiveness, cost and patient preference. Much development and evaluation work remains to be done, again as highlighted by NICE.
2. However, current central funding arrangements threaten to undermine and weaken this work and the UK's pre-eminence because the allocation of the excess treatment costs necessary for such clinical investigations is complex and does not operate effectively. Definitions of treatment, and excess treatment, costs are set out in: The Department of Health Guidance Document 'Attributing revenue costs of externally-funded non-commercial research in the NHS (ARCO)' (Gateway reference: 5956) of December 2005, which states:

‘Treatment Costs are the patient care costs *which would continue to be incurred if the patient care service in question continued to be provided after the R&D activity had stopped*. Where patient care is provided that is either an experimental treatment or a service in a different location from where it would normally be given and it differs from the normal, standard treatment for that condition, the difference between the total Treatment Costs and the costs of the standard treatment (if any) is called Excess Treatment Costs. These costs are nonetheless part of the Treatment Costs, not an NHS Support or Research Cost. The term Treatment Costs covers all types of patient care services, including diagnostic, preventive, continuing-care and rehabilitative-care services, and health promotion.’

3. The normal expectation by the Department of Health is that these excess treatment costs, which fall outside the NHS R&D budget, are sought through commissioning arrangements via PCTs. Exceptionally it has been possible for those conducting clinical trials and other clinical studies to seek excess treatment costs from central Department of Health subvention. More recently, however, central subvention for the excess treatment costs relating to research has become more variable and increasingly difficult to establish. This threatens the capacity to run large-scale trials, such as those of psychological therapies, because:

(a) Local NHS commissioners will usually only fund existing treatments. They are often understandably reluctant to fund new therapies until they have been shown to be effective and better than those that are already available in the NHS.

(b) New therapies need to be delivered by clinicians who are fully trained in the innovative procedures. This is realisable with a centrally funded expert therapeutic teams, but difficult to achieve with routine NHS clinicians who are temporarily seconded to a project and have many competing clinical demands. In mental health care the treatment cost issue applies particularly to innovative psychological and social treatments, where individual and specifically trained therapists are required to provide the complex treatments, whereas pharmacological trials can normally be conducted by arranging for the usual clinical staff to prescribe and administer the intervention.

(c) Multi-centre trials are often needed to provide a definitive evaluation of a new treatment. Separate negotiation of therapist costs from multiple local NHS organisations is bureaucratically cumbersome, and can engender substantial delays before projects can start. Absence of central funding also undermines consistency and control of therapy delivery across sites.

4. We also wish to emphasise the need for the single fund allocation system to distribute funds in such a way that recognises different clinical environments that incur different costs. In particular, we emphasise that much mental health service provision takes place in the community and thus associated research costs need to reflect the high level of contact with community mental health teams, which are generally higher than the costs of inpatient/outpatient hospital oriented research. There are also additional costs associated with recruitment of some hard to reach participants, particularly within mental health services.

5. These points pose severe current threats to the development and evaluation of innovative treatments, including novel psychological and social therapies, with adverse implications for the UK's international position in this area as well as for the NHS. It is therefore to be hoped that new funding arrangements will address the need for combined funding of therapy provision and evaluation costs to ensure that high quality studies of new treatments that are expected to have a substantial impact on the NHS can take place.

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Signed on behalf of the South London and Maudsley NHS Trust:

A handwritten signature in black ink, appearing to read "Stuart Bell". The signature is written in a cursive, flowing style.

Mr Stuart Bell, Chief Executive

Signed on behalf of the Institute of Psychiatry, King's College London:

A handwritten signature in black ink, appearing to read "George Szukler". The signature is written in a cursive, flowing style.

Dr George Szukler, Dean