

**SUPPLEMENTARY STATEMENT OF SIR KENNETH CALMAN**

1. This supplementary statement provides the additional information which I promised the Inquiry during my oral evidence on 20<sup>th</sup> October 1999.

**MANAGED INTRODUCTION OF NEW SURGICAL INTERVENTIONS**

2. I was asked about the system for ensuring that the introduction of new surgical techniques is managed effectively.
3. I have set out below the procedures already established before I left the Department of Health in 1998, but for completeness I have consulted with former colleagues and also describe any current and future initiatives.
4. The principle safeguard – beyond the work of local ethics committees – is the Safety and Efficacy Register of New Interventional Procedures (SERNIP). This voluntary system, which is independent of the Department of Health, was set up under the auspices of the Academy of Medical Royal Colleges in 1996 and continues to receive funding from the Department of Health.
5. SERNIP is staffed by a part-time clinical director and a full-time administrator, and is supported by an Advisory Committee whose membership includes 11 representatives of the Medical Royal Colleges, and representatives from the Standing Group on Health Technology, the Medical Research Council and the Medical Devices Agency. The Department of Health has observer status on the Committee.
6. A clinician when considering introducing an innovative procedure into his/her clinical practice is encouraged to contact the SERNIP office; alternatively, the enquiry may come from a Trust or commissioner. If the procedure in question is already on the register, the SERNIP office notifies which of four categories it has been assigned to. If it is not on the register,

they arrange for an assessment of the intervention by a professional advisory committee, based on the published literature, to assign a category.

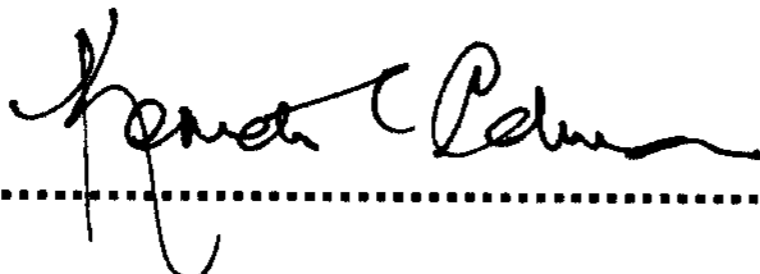
7. In their current form the four categories are:
- Safety and efficacy established; procedure may be used
  - Efficacy established. Further evaluation required to confirm safety: procedure can be used as part of a surveillance programme registered with SERNIP
  - safety and efficacy not proven: should be used only as part of a primary research programme, using appropriate methodology and registered with SERNIP
  - safety and/or efficacy shown to be unsatisfactory, should not be used.

The Committee's advice is then notified to the clinician who raised the original enquiry. A summary of SERNIP'S recommendations is also circulated to health authorities. SERNIP has so far categorised over 100 operations and procedures.

8. If a surgical intervention involves the use of a *medical device*, the device is subject to statutory regulation under the terms of two European Directives (a third directive covering in-vitro diagnostics will come into force in June 2000). Essentially, these provide safeguards about the safety and performance of the device, in particular that any risks associated with use of the device are acceptable when weighed against the benefits to patients. The Directives also establish procedures for post-market surveillance and reporting of adverse events. The competent authority in the UK for overseeing the application of the Directives is the Medical Devices Agency (MDA).

**CURRENT AND FUTURE INITIATIVES**

9. The processes already referred to do not in themselves guarantee that a new intervention will produce improved clinical outcomes under real life conditions in the NHS, or at a proportionate cost. This is the task of the newly established National Institute for Clinical Excellence (NICE). The Institute will develop condition-based clinical guidelines and audit methodologies, and will also carry out 30-50 appraisals of individual clinical interventions each year. These will include both new and existing interventions, selected in order to focus on those with potentially the most significant health benefit for patients and/or the greatest impact on NHS resources. The current work programme includes an appraisal of laparoscopic surgery in the treatment of hernias and colorectal cancer, and of a new technique for autologous cartilage transplantation.
10. The Department of Health and the Academy of Medical Royal Colleges are currently reviewing SERNIP. In particular they are considering the steps needed to ensure the participation of clinicians across all relevant specialties; detailed aspects of the process, including the possible need for a formal "appeals" procedure; and relations to the MDA and NICE.

Signed.....  ..... Dated..... 14.12.99 .....