

Appendix - Paediatrics

Accreditation of Respiratory Function Assessment Services Paediatric Modules

Module M: Introducing New Technologies

It is essential to collect and assess evidence based information in regard to the safety and efficacy of any new technologies and procedures.

Within an organisation, an agent such as a physician, surgeon, nurse, allied health professional or scientist will recommend introducing a new technology or procedure to the director of their relevant division. The director would then forward this submission to a review group. In many health organisations, this may be a Credentialling Committee. The review group should consist of people skilled in the particular discipline as well as those with expertise in the technology, research and associate disciplines. The review group will make a recommendation to the appropriate management committee.

The review group will have established criteria for systematic review. These will include referral patterns for the procedure, demand, impact on waiting lists, budget, safety, comparability with other procedures, efficacy and outcome. There will be a review of literature and an assessment of prior evaluation.

Many techniques will have been evaluated or at least implemented elsewhere and the assessment should consider

1. Has the technique been previously evaluated?
2. How reliable is the evaluation? This would include an analysis of the robustness of the evidence i.e. study design, numbers, reliability of morbidity and mortality data, consideration of confounding factors, the patient cohort reported.
3. The complexity of the procedure is important as it may be associated with greater risk. Accuracy, efficacy and safety need more intensive consideration.

The assessment must determine whether the institution has experience in similar procedures and is capable of providing the infrastructure support for the technology or procedure. This would include an assessment of staff experience. The assessment should determine whether individuals recommending the new technology or procedure have any conflict of interest and in particular, any financial involvement which may lead to a perception of bias.

Resource utilisation must be fully assessed with present and future costs of the new procedure estimated as accurately as possible. It must be determined whether adequate resources and facilities within the organisation are available to implement the new technology or procedure. It is important to determine whether the through-put will be adequate to ensure that necessary skill levels are achieved and maintained.

The application should include draft patient information and informed consent forms for use of the new technology or procedure. Potential risks of the new procedure should be outlined as accurately as possible. Adequate resourcing is needed for review and further testing, if required.

With available evidence the review group will recommend to the management committee whether unconditional approval should be given or whether conditional approval is more appropriate so that the procedure can only be undertaken by specified individuals or for

specific indications. It may also be appropriate for certain patient categories or it may only be appropriate in the context of a control clinical trial.

Following approval, there should be dissemination of the decision and appropriate introduction and monitoring of the usage. The procedure must be described in detail in a manual and criteria for appropriate quality control implemented. Accurate recording of details of the procedure including factors such as the purpose, the equipment used, calibration procedures, troubleshooting, specific quality control steps, cleaning and maintenance, infection control and safety requirements, interpretation of the findings. Confidentiality must be assured. Monitoring of safety and efficacy and a database for patient feedback must be in place. Provisions for staff development should be documented and provisions for unexpected emergencies recorded.

An opportunity for mediation is important should the applicant for the new technology or procedure have a dispute with the management committee.

A continuing quality assurance program must include regular collection of relevant data, periodic assessment of the data to identify problems or opportunities to improve, actions to address such problems or opportunities, and evaluation of the effects of such actions, regular communication to the staff and management.

Relevant websites re 'Introducing New Technologies' are:

The International Network of Agencies for Health Technology Assessment.

<http://www.inahta.org>

The Medical Services Advisory Committee.

<http://www.health.gov.au/msac>

The Therapeutic Goods Administration.

<http://www.health.gov.au/tga>

Royal Australasian College of Surgeons Guidelines.

<http://www.surgeons.org/wedo/publications>