

Title: INTRODUCTION OF NEW CLINICAL PROCEDURES, TECHNOLOGIES OR TREATMENTS

<p>Policy Statement:</p> <p>The purpose of this policy is to define the requirements for introducing new procedures, technologies or treatments into clinical practice at Osborne Park Hospital (OPH).</p>	<p>Code:</p> <p>Areas Covered: Osborne Park Hospital</p> <p>Page 1 of 4</p>
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Procedure

The introduction of new procedures, technologies and treatments to Osborne Park Hospital must be done in a manner that ensures patient safety and welfare. They should only be introduced when their clinical benefit is proven or the likelihood of clinical benefit is proven, and when the individual practitioners can extract the clinical benefit from them.

Failure to adequately assess new procedures, technology and treatments, and credential medical practitioners appropriately may place patients at risk of harm and the hospital at risk of legal liability. If there is doubt about the safety of the procedure, technology or treatment (henceforth referred to as PTT(s)) then approval should not be given to proceed.

The use of a new drug or blood product at OPH should be considered by the combined Drug and Therapeutics/Transfusion Committee according to its Terms of Reference. The use of an expensive new drug, as defined by the WA Drug Evaluation Panel (WADEP), may be referred to that Panel for consideration if it has not already been reviewed. The relevant application forms are available from the WATAG website. Restrictions placed on the use of drugs by the WA Therapeutic Advisory Group (WATAG) should be considered by the Drug and Therapeutics Committee, but the decision to provide the drug through OPH rather than one of the tertiary sites, will depend on the availability of funding. In the ensuing discussion of new PTTs, drugs subject to these processes will not be considered further. However the Drug and Therapeutics/Transfusion Committee may choose to refer the use of new blood products for consideration as a new technology.

A new PTT may be proposed for introduction to OPH:

- as a planned introduction of a new service
- as a planned expansion of an existing service
- at the suggestion of a medical practitioner

Distinctions should be made between:

- 1 Medical practitioners seeking to expand their Scope of Clinical Practice at OPH within the range of PTTs already performed there and within the Scope of Clinical Practice of other doctors at that site. In such cases the medical practitioner needs to demonstrate that;
 - they have been trained appropriately and that they have the necessary skills to carry out the procedure(s) at OPH (responsibility of the relevant Credentialling Committee).

Endorsing Authority:		References
Policy or Procedure Sponsor	Medical Co Director	<p>OSQH Policy for Credentialling and Defining the Scope of Clinical Practice for Medical Practitioners (2nd Edition)</p> <p>Women and Newborn Health Service: W114 Assessing New Clinical Technologies/ Techniques. Sept, 2008.</p> <p>Royal Australasian College of Surgeons: General Guidelines for Assessing, Approving and Introducing New Surgical Procedures into a Hospital or Health Service</p>
Original Issue:	February 2009	
Last Amended	February 2009	
Review Date	February 2010	
Standards		
EQuIP	4 th Edition	
Legislation		
Standard	2.2, 3.1	
Criterion	2.2.2, 3.1.3	
Related Documents		

Procedure continued

- 2 Medical practitioners seeking to expand their Scope of Clinical Practice at OPH to include other PTTs, which have already been assessed and are already part of routine care at other sites. In such cases the medical practitioner needs to demonstrate that;
 - it is appropriate for the PTT to be introduced at OPH (responsibility of the OPH Executive Committee)
 - OPH has the necessary resources, skill mix and funding to support that PTT (responsibility of the OPH Executive Committee), and that
 - they have been trained appropriately and have the necessary skills to carry out the procedure(s) at OPH (responsibility of the relevant Credentialling Committee).
- 3 Medical practitioners seeking to expand their Scope of Clinical Practice at OPH to include *novel* PTTs, which have not already been assessed and are not already part of routine care at other sites. In such cases the medical practitioner needs to demonstrate that
 - a technology appraisal has been performed by an appropriate body (responsibility of the relevant Credentialling Committee; in WA, WAPACT or WADEP would be the appropriate panels for expensive new technologies and drugs respectively)
 - it is appropriate for the new PTT to be introduced at OPH (responsibility of the OPH Executive Committee),
 - OPH has the necessary resources, skill mix and funding to support that PTT (responsibility of the OPH Executive Committee), and that
 - they have been trained appropriately and have the necessary skills to carry out the procedure(s) at OPH (responsibility of the relevant Credentialling Committee).

In each case the initial request should be made to the relevant Head of Clinical Service, who will:

- decide whether the suggestion should be supported and/or investigated
- refer the matter to the relevant Service Management Committee and if necessary
- provide the completed documentation for the relevant Credentialling Committee.

For applications related to the Women's and Newborn Service, the relevant Committee will be the Credentialling Committee at King Edward's Memorial Hospital (KEMH); in all other cases it will be the Credentialling Committee for the North Metropolitan Area Health Service.

Situation 1 (above) will be considered as an application for an extension of the applicant's Scope of Clinical Practice (see OPH Policy on Credentialling and Defining the Scope of Clinical Practice). The process for dealing with situations 2 and 3 (above) will be discussed further, below.

The Medical Co-Director needs to consider whether:

- OPH has the necessary resources to support the safe provision of a new PTT,
- the source of funding has been agreed,
- the new PTT should be further considered for implementation at OPH.

The Medical Co-Director may then:

- support the introduction of a routine technology,
- refer the matter to the OPH Executive Committee, Medical Executive Committee and/or Service Management Committees for further consideration and/or
- refer the matter to the relevant Credentialling Committee.

Responsibilities

The Medical Practitioner and Head of Clinical Service are responsible for:

- Providing a written application to the Medical Co-Director for assessment/credentialling to introduce new procedures, technologies or treatments.
- Preparing the application in accordance with the published guidelines of the relevant Credentialling Committee (see above).

- Ensuring that the information to be presented to the patient to obtain consent to the procedure is included with the application.

The Medical Co-Director is responsible for:

- Providing advice to medical practitioners on the preparation of applications for new procedures, technologies and treatments.
- Ensuring that the application is considered by the appropriate Credentialling Committee.
- Notifying the outcome to the applicant
- Notifying the relevant Heads of Clinical Service and Medical Executive Committee
- Arranging the review in the event of an appeal.
- Ensuring that the appropriate clinical audit is undertaken of the new procedure, technology or treatment and the results presented to the appropriate Credentialling Committee for review.

The Credentialling Committee is responsible for ensuring that:

- The applicant has demonstrated that the new procedure/technology/treatment:
 1. Is technically sound
 2. Leads to or has the potential for clinical improvement
 3. Is logistically implementable
 4. Is financially viable
 5. Is consistent with the role delineation of OPH
 6. Is ethically acceptable (eg. Does the patient give consent?)
- The applicant has demonstrated that he/she:
 1. Has sufficient training in the appropriate techniques
 2. Has sufficient exposure to maintain these skills
 3. Has the skills or back-up for an alternative procedure if required
 4. Is prepared to collect data for peer review related to patient outcome as a result of the introduction of the new procedure/technology/treatment.

For further information on assessment refer to the Terms of Reference for North Metropolitan Area Health Service or King Edward Memorial Hospital Credentialling Committee.

If consideration from the Ethics Committee is deemed necessary by the Credentialling Committee then the application is reviewed taking into account any recommendations made by the Ethics Committee.

Where the results of the implementation of a new procedure/technique/treatment are considered by the peers to be of concern, then appropriate review of the procedure/technology/treatment is undertaken and remedial action is instituted or the clinical privileges related to the new procedure/technology/treatment are suspended.

The Osborne Park Hospital Executive is responsible for ensuring that:

- New procedures/technologies/treatments are introduced at OPH only after the appropriate approval has been obtained under this policy.
- Processes outlined in this policy are followed.

Guidelines for Applicants

Assessing New Procedures/Technology/Treatments

The proponent of the new procedure/technology/treatment has to demonstrate to the Credentialling Committee that it is demonstrably safe, effective and cost efficient. This will need to be done with reference to appropriately refereed literature, presentations and/or other studies. In the absence of cost effectiveness, clinical effectiveness or widespread support behind the proposal, the hospital is unlikely to commit resources to the introduction of the new procedure/technology/treatment.

Demonstrating Individual Expertise in Undertaking the New Procedure/Technology/Treatment

The applicant must provide documentation of experience showing his or her competence in the particular technique. Where possible this documentation should be correlated against agreed College, Society or Hospital credentialling guidelines for this or related procedures. It is important to ascertain that the applicant

is capable of managing any complications of the new procedure/technology/treatment. It should be made clear that in the event of any complications the applicant has the expertise to initiate a back up procedure or has an agreement with another clinician who can perform the back up procedure in a timely manner.

Training of New Operators

The Credentialing Committee, in collaboration with the OPH Medical Co-Director and relevant Head of Clinical Service, should define guidelines as to what designates appropriate training and maintenance of skills for new operators.

Informed Consent

- The patient (and family) needs to be advised that the procedure/technology/treatment is new and/or experimental.
- Potential risks of new procedures/technology/treatments, including any areas of uncertainty, should be outlined to patients as accurately as possible.
- Information should be provided about the criteria for selection of patients for the new procedure/technology/treatment, as well as alternative treatments which are available.
- Patients should be able to access information about how many of these procedures have been performed at OPH and by the medical practitioner who will perform the procedure.

