PURPOSE

All new clinical interventions at Bay of Plenty District Health Board (BOPDHB) will be assessed, approved, introduced and evaluated in a safe manner to protect the interests of patients, clinicians and BOPDHB.

STANDARDS TO BE MET

1. Prior assessment of the intervention

1.1. All new interventions must be fully assessed. Simple questions may be asked in the first instance, for example;
   a) Has the technique been evaluated before?
   b) How reliable is the evaluation?
   c) How wide ranging or complex is the procedure?
   d) Are there randomised controlled trials of the intervention?
   e) What are the additional costs of the new intervention?

1.2. There are several aspects to be taken into account for prior assessment of a new intervention. Clinicians must consider the following;
   a) The new intervention must be evidence-based with perceived advantages of the new versus the old intervention assessed in the light of clinical evidence.
   b) Although a new intervention may have been evaluated elsewhere, local requirements and availability of resources may differ and must be taken into account.
   c) Whilst the decision whether to introduce a new intervention can open up opportunities to advance knowledge and increase the experience of staff, it can also present a threat to the safety of patients and therefore a full risk assessment must be made.
   d) New interventions must comply with current NZ legislation, such as the Code of Rights and Privacy Act.
   e) New interventions must have a full cost benefit analysis performed bearing in mind that it will consume finance and resources that would have been used elsewhere. It must also fit within overall service planning. Consultation with the General Manager of Planning and Funding may be necessary.
   f) New interventions need to align with BOPDHB strategic priorities.

1.3. Consideration must be given to the predicted throughput of cases likely to present in order to allow maintenance of required skill levels.
   a) If any equipment or plant is required, consider the ongoing costs, including maintenance of this, whether the DHB has the resources to do this and how any “down time” or failure of this will be managed.
   b) Any ethical, social, political or legal issues must be considered.
   c) The Maori Health team must be consulted for any cultural considerations surrounding the intervention.
   d) Consideration must be given to the impact of the new intervention on nursing, allied health and support staff, including cost and workload.
   e) Consider consultation with external bodies such as the Health and Disability Ethics Committee or professional bodies and colleges.

2. Approval process

2.1 Any clinician wishing to introduce a new clinical intervention at BOPDHB must obtain approval prior to doing so from the;
   a) appropriate Head of Department
   b) Service Medical Leader, Nurse Leader and Business Leader
   c) the Chief Medical Advisor(CMA) / Medical Director
   d) BOPDHB Clinical Board
   e) Chief Operating Officer (COO)
   f) BOPDHB Credentialing Committee.

2.2 As referred to above, there may be an additional requirement for approval from the Planning and Funding Department.

2.3 Any conflict of interest or financial involvement of clinicians must be declared on the application for approval.

2.4 The Form FM.N3.1 New Clinical Interventions Application must be completed and sent to the CMA / Medical Director in the first instance and this will be submitted to the Clinical Board and the COO.

2.5 All applications will be held by the CMA / Medical Director office.

2.6 Approved applications will be forwarded to the Service Business Leader for incorporating into a business case to follow normal approval process.

2.7 Declined applications will be held by the CMA / Medical Director office as per the Public Records Act requirements.

3. Patient selection

3.1 Patient selection criteria must be clearly defined and adhered to.

3.2 Patients must be provided with the selection criteria. Patients must be informed that this is a new intervention for BOPDHB and whether or not there exists a trial period for its introduction. Application of the new intervention to patients must only occur following fully informed consent.

3.3 Patients should also be able to access information about how many interventions have been provided at BOPDHB and by any individual clinician.

4. Data collection and record keeping

4.1 Structured monitoring and data collection of the new intervention must be established prior to the first intervention.

4.2 Records must be kept in accordance with the NZS 8153:2002 – New Zealand Standard for Health Records.

5. Progress reports

5.1 It is good clinical practice to provide regular progress reports on a new clinical intervention. These should be provided to the Head of Department at stated and at agreed intervals throughout the trial period.

5.2 Criteria must be set for the type of adverse events and outcomes that would call a halt to continuing the new intervention.

5.3 Should any issues arise that require a decision to cease the new intervention, this should be reported to the CMA / Medical Director.

5.4 FM.N3.2 Progress Report Template.

6. Reportable Events

6.1 Any reportable events arising from a new clinical intervention must be reported as per BOPDHB policy 2.1.4 Incident Management. The National Reportable Events Policy directs that "near miss" events must also be reported.

6.2 Open disclosure with consumers, families / whanau must be practised. Refer to the BOPDHB policy 2.1.4 protocol 3 Incident Management - Open Disclosures.

6.3 Any systems changes made as a result of a reportable event must be considered for dissemination both locally within the DHB and if appropriate, nationally through the Health Quality & Safety Commission.

7. Evaluation

7.1 An initial trial period must be set with a planned evaluation to be carried out at the end of the trial period.

7.2 All new clinical interventions must have a comprehensive evaluation carried out to establish efficacy and safety. The evaluation will take into account:

a) Any adverse events occurring from the intervention
b) The overall patient benefit derived from the new intervention
c) The additional costs of the new intervention considered over the whole trial period.
d) The effect of the additional training and workload on all staff including nursing and allied health.

ASSOCIATED DOCUMENTS

- Bay of Plenty District Health Board policy 2.1.8
- Bay of Plenty District Health Board policy 2.1.7 Research
- Bay of Plenty District Health Board policy 1.1.1 Informed Consent
- Bay of Plenty District Health Board policy 2.1.4 Incident Management
- Bay of Plenty District Health Board policy 2.1.4 protocol 3 Incident Management - Open Disclosures
- Bay of Plenty District Health Board policy 2.1.1 Risk Management
- Bay of Plenty District Health Board policy 2.1.3 Hazard Management
- Bay of Plenty District Health Board Form FM.N3.1 New Clinical Interventions Application
- Bay of Plenty District Health Board Form FM.N3.2 New Clinical Interventions Progress Report

Appendix 1: Process for Introducing a New Intervention