

NATIONALLY FUNDED CENTRES PROGRAM

GUIDANCE

FOR

GOVERNANCE, MANAGEMENT, FUNDING, ESTABLISHMENT, REVIEW

(www.nfc.sa.gov.au)

AUSTRALIAN HEALTH MINISTERS' ADVISORY COUNCIL

September 2011

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SECTION 1 – BACKGROUND

At the June 1990 Australian Health Ministers Conference (AHMC), Ministers endorsed a national policy for public sector provision of high cost, highly specialised clinical practices and technologies with limited demand. This is the Nationally Funded Centres (NFC) Program.

SECTION 2 – PURPOSE OF THE NFC GUIDANCE DOCUMENT

The purpose of the *Nationally Funded Centres Guidance for Governance, Management, Funding, Establishment, Review* (the NFC Guidance document) is to ensure that there is accountability and transparency in NFC processes. In summary, the NFC Guidance document provides information on the following:

- governance, management, administration and funding of the NFC Program;
- nomination processes for a proposed NFC;
- assessment of proposed NFCs;
- establishment of new NFCs;
- review of NFCs; and
- cessation of a NFC.

Enquiries in regard to the NFC Program should be made in the first instance to the relevant jurisdictional department of health.

SECTION 3 – PROGRAM OBJECTIVES AND OVERVIEW

The objectives of the NFC Program are to ensure that:

- there is optimal access to certain high cost, low demand, new and emerging technologies regardless of geographical location, in the context of workforce and resource availability;
- these technologies are provided efficiently and effectively;
- requirements for high quality and safe introduction and ongoing provision of these technologies have been defined and implemented; and
- health and cost outcomes of these technologies are monitored and evaluated.

For a technology to be considered for provision as a NFC it must be an established clinical practice requiring a national population base for efficient and effective service provision. A technology may be considered if it is a clinical practice in the establishment phase and has yet to be incorporated into standard clinical practice, but has the potential for broader diffusion into the Australian health system.

The scope of technology eligible for consideration as a NFC includes devices, prostheses, techniques, skills or expertise (or personnel with particular skills or expertise) and/or procedures, or combinations of these.

High cost, low demand pharmaceuticals are not eligible to be considered for the NFC Program unless they are an essential component of care in the provision of a particular practice or technology.

Delivery of technologies approved as part of the NFC Program may occur in one or more designated sites, and is restricted to those sites.

Where a technology is delivered at only one site, risk management strategies should be articulated in the event that the service could not be provided at the site due to workforce issues or other unforeseen circumstances.

Provision of some technologies as a NFC will be long-term, whilst others will be for a shorter term as the practice becomes more established and it is clinically appropriate to diffuse across the health system.

In some instances, approval to provide a technology as a NFC may be withdrawn as a result of evidence becoming available subsequent to approval.

Funding for NFCs is provided by State and Territory jurisdictions according to a weighted population-based formula and based on an agreed price for each procedure.

NFCs will provide services to overseas residents if this does not impede access for Australian residents. Overseas residents (including New Zealand residents) will be charged the full cost of the service, subject to any reciprocal arrangements (for immediate and necessary care) agreed with the overseas country. If reciprocal arrangements exist and apply to the circumstances and treatment received by the overseas patient, then the NFC Program will pay for the procedure. Where a funding claim for an overseas resident is made under the NFC Program, necessary clinical and administrative details will be shared to the satisfaction of the NFC Reference Group.

SECTION 4 – GOVERNANCE, MANAGEMENT, ADMINISTRATION AND FUNDING

4.1 GOVERNANCE

AHMC assigned oversight of all aspects of the NFC Program and associated policy to the Australian Health Minister's Advisory Council (AHMAC).

4.2 MANAGEMENT AND ADMINISTRATION

The NFC Reference Group reports to AHMAC through its Clinical, Technical and Ethical Principal Committee (CTEPC) and is responsible for:

- the planning and management of the NFC Program, including determination of the annual budget for the NFC Program and the NFC Secretariat;
- ensuring submissions for new NFCs are assessed (subsequent to approval by AHMAC through CTEPC);
- reviewing existing NFCs every three years, or at other times as indicated; and
- monitoring the activity and outcomes of NFCs between reviews.

The NFC Reference Group will include a representative from the Australian Government, and each State and Territory, and will meet as required. A nominee of HealthPACT may attend NFC Reference Group meetings as an observer.

Administration of the NFC Program is undertaken by a host jurisdiction nominated by AHMAC. The host jurisdiction will establish a NFC Reference Group Secretariat (the NFC Secretariat) for this purpose.

An assessing body will be engaged by the NFC Reference Group on behalf of AHMAC to undertake a health technology assessment for each proposed new technology / clinical practice as required. The assessing body will provide recommendations to the NFC Reference Group on the establishment, or not, of new NFCs. The NFC Reference Group will then review the recommendations in conjunction with a range of policy and service planning issues in order to make recommendations to AHMAC through CTEPC. The NFC Secretariat will prepare a report to AHMAC through CTEPC, based on consideration of the assessing body's recommendations.

For further details of the assessment process for new NFCs, refer Section 5.

Reviewing bodies will be engaged by the NFC Reference Group on behalf of AHMAC to review existing NFCs and make recommendations on the continuation or cessation of existing NFCs. The reviewing body will provide recommendations to the NFC Reference Group on the immediate future of the NFC(s), up to the time of the next review. The NFC Reference Group will then review the recommendations in conjunction with a range of policy and service planning issues in order to make recommendations to AHMAC through CTEPC. The NFC Secretariat will prepare a report to AHMAC through CTEPC, based on consideration of the reviewing body's recommendations.

For further details of the review process for existing NFCs, refer Section 6.

The NFC Reference Group will ensure appropriate project management of the required assessments and reviews in consultation with the assessing/reviewing body. This will include consideration of:

- structures and processes to undertake the work;
- roles and responsibilities;
- consultation and site visits;
- scope and content of the required work;
- timeliness of work plans;
- progress reporting requirements; and
- communication arrangements to ensure issues can be addressed as they arise.

For further details of roles and responsibilities of various groups in relation to the NFC Program, refer Appendix 1.

4.3 FUNDING

Funding is currently provided for the NFC Program by the State and Territory jurisdictions. This includes funding for individual NFCs, the cost of the NFC Secretariat and the cost of any planned assessments and reviews in a given financial year.

When the NFC Program was first established Health Ministers agreed that NFCs would be funded from a pool established by contributions from the Australian Department of Health and Ageing and all States and Territories. However, since 1998 the Department of Health and Ageing has broad-banded its contributions initially through the Australian Health Care Agreement and, since 1 July 2009, the National Healthcare Agreement.

Contributions are now received from each of the States and Territories based on a weighted population-based formula. The funds are pooled into a separate fund which is operated by the AHMAC Secretariat on behalf of the NFC Program.

The funds held by the AHMAC Secretariat are in turn paid to those jurisdictions that are net recipients of funds (that is they are owed more for the NFC procedures they undertake than they owe for their share of the costs of the NFC Program as a whole).

The price for existing NFC procedures is indexed annually by an amount reflecting the Australian Institute of Health and Welfare health-specific cost index and the Productivity Commission derived index of technology growth, as used for the National Healthcare Agreement growth factor.

4.4 COST OF PROCEDURES AND SERVICES

The funding of each NFC site is calculated based on the agreed cost of the procedure performed at that NFC site, multiplied by the anticipated number of patients per annum. Initially the cost of the procedure will be determined on the basis of the care pathways and costings provided in the submission for a new NFC, taking account of the advice provided by the assessing body. The NFC Reference Group may choose to engage an independent consultant for a more detailed costing study.

For costing pro forma refer to Appendix 2.

A clear definition of the start and end point for an episode of care of an individual NFC procedure is required. In general, the jurisdiction will pay for the patient until the patient is accepted onto the NFC Program and the NFC Program pays from then to three months post discharge, after which the jurisdiction will again be responsible for the patient costs. There may be exceptions to this general scope depending on the type of procedure funded under the program.

When an assessment is being made about the appropriateness of a technology for NFC status, consideration will be made in regard to the scope of the episode of care to include:

- the elements of preliminary care which are regarded as highly specialised, high cost and/or need to be undertaken by the NFC team; and
- the elements of post care which are regarded as highly specialised, high cost and/or need to be undertaken by the NFC team.

Total costs will include the inputs and costs associated with pre care activities and the inputs and costs associated with any post treatment and follow up care.

One of the objectives of the NFC Program is to ensure optimal access for Australians to approved NFC procedures regardless of geographical location, in the context of workforce and resource availability. To ensure equity of access to the NFC sites, total costs include travel and accommodation for interstate patients and their family/carer.

In general, funding will not be considered for different clinical pathways for an agreed procedure. However, consideration may be given to multiple pathways where the cost differentials are significant and the numbers involved are material. This will be considered on a case by case basis by the NFC Reference Group, along with the determination of what is deemed to be significant and what is deemed to be material. The NFC funding provided should be reasonably commensurate with costs of the NFC part of a service.

If there are multiple sites for a single procedure, in general, the NFC Program will pay the lesser price for all sites. However, the NFC Reference Group will consider variations to the 'lesser price' principle on a case by case basis where the lesser price is determined to be inadequate.

Cost data will be required from jurisdictions in the following four circumstances:

1. when nominating jurisdictions provide a detailed submission in support of a proposed new NFC (refer section 5.2);
2. when jurisdictions provide information to support their expression of interest to host a site during the process of establishing a new NFC (refer section 5.5);
3. when an existing NFC is being reviewed (refer section 6); and
4. when a jurisdiction is seeking a change in the NFC price at a time after establishment, and before the next scheduled review (refer section 6.1).

The NFC Reference Group will proactively monitor changes in costs as part of the annual reporting by NFCs.

The NFC Reference Group will review the NFC costing methodologies and funding model every three years.

4.5 ANNUAL BUDGET DETERMINATION AND DISBURSEMENT OF FUNDING

The NFC budget is determined each year by the NFC Reference Group on the basis of activity estimates derived from trends in previous years and anticipated activity for the coming year. If there is more than one NFC site providing the same procedure, each site will receive the same price per procedure. The price per procedure is indexed annually.

The NFC sites will be required to operate within their budgets with no adjustments for variations in procedures within the current financial year. Any cost overruns are to be met by the jurisdiction in which the NFC is located. However, the NFC Reference Group will make an adjustment each budget cycle for more or less procedures undertaken in the previous year, above or below the estimated number of procedures funded for that year.

Where an episode of care straddles two financial years, the date of the procedure (recognising however that some NFCs have more than one procedure) is the date used to determine the financial year within which the approved NFC procedure has been undertaken for annual reporting and funding purposes. However, the NFC Reference Group may approve variations to this general rule on a case by case basis as long as the variation is consistently applied from year to year. If in doubt, the site should seek clarification from the NFC Reference Group via their jurisdictional representative.

In addition to the cost of providing the NFC procedures, the jurisdictions will also be required to make a contribution towards the following:

- cost of running the NFC Secretariat; and
- costs of assessments and reviews if required.

The contribution from each State and Territory is based on the percentage of their weighted population to the total weighted population of Australia.

The steps in budget determination, funding allocation and disbursement are as follows:

1. ***NFC annual reporting requirements:***

By mid July each year NFC sites must submit, via their jurisdiction, data on the actual number of procedures performed in the previous financial year and the estimated number of procedures to be performed in the current financial year. A pro forma is forwarded to the NFC for this purpose. Refer Appendix 3.

2. ***Draft budget:***

Subject to the timely receipt of data, the NFC Secretariat will provide a consolidated draft budget to the NFC Reference Group members by the end of July each year. The draft budget will include:

- the estimated number and type of procedures by NFC for the current year;
- adjustments for the difference between the estimated and actual number of procedures performed in the previous year;
- agreed price per procedure for the current year reflecting the previous years' price and the approved annual indexation;
- costs for running the NFC Secretariat;
- costs for assessments and reviews if required;
- the total contribution of each State and Territory, derived from the weighted population formula; and
- the net payments to States or Territories with NFC sites where the amount they owe for their share of the procedures is less than the payment owed to them for the actual undertaking of procedures.

3. ***Budget consultation:***

Jurisdictional responses to the draft budget should be provided to the NFC Secretariat promptly, and by mid-August at the latest. The response may be agreement to the draft budget or a request for justification of budget estimates for further consideration. All requests for additional information should be directed through the NFC Secretariat.

4. ***Final budget:***

The NFC Reference Group meets at the end of August each year and agrees to the final budget. The NFC Reference Group will provide an out of session briefing to AHMAC through CTEPC on the budget for noting.

5. ***Invoicing:***

In early September, the NFC Secretariat makes a formal request to the AHMAC Secretariat to send two invoices to the States and Territories requesting their contribution for:

- the NFC Program (cost of the NFC approved sites) (GST exclusive); and
- administration costs which includes the NFC Secretariat and the cost of any assessments and reviews (if required) (GST inclusive).

Jurisdictions hosting NFCs will be paid or will be required to pay the difference between the amount they should pay for their weighted population share of the NFC Program costs and the payment owed to them as a NFC provider for the procedures they anticipate they will undertake, depending on which amount is greater. For these jurisdictions they will either receive an invoice for the net amount required to be paid to the NFC Program or will be asked to generate an invoice to the AHMAC Secretariat for the net receipts they are owed.

6. **Payments:**

Jurisdictions will make their contributions by the end of September. For net recipients, the NFC Secretariat, through the AHMAC Secretariat, will make one annual payment, in October each year.

4.6 ANNUAL REPORTING REQUIREMENTS

NFC sites will be required to provide annual reports by mid-July each year and report on the following:

- patient numbers and demographics;
- patient outcomes specific to, and as agreed, for individual NFCs;
- quality and safety indicators including:
 - adverse clinical events;
 - unplanned readmission to intensive care;
 - unplanned readmission post discharge;
 - quality of life;
 - patient / family / carer satisfaction; and
 - other specifics as agreed with individual NFCs;
- an update on the status of the technology;
 - an update of the status and associated patient outcomes in international jurisdictions;
 - any changes in the initial estimation of demand for the service and why;
 - any significant modifications to the treatment being provided by the NFC along with the cost implications and evidence to support these modifications;
- cost measurement;
- progress on any NFC review recommendations related to the specific NFC; and
- activity plan for the upcoming financial year;
 - anticipated demand and estimated number of procedures;
 - intended activities in relation to outreach services;
 - staff training and development, and workforce sustainability; and
 - expected changes to the nature of the service delivery.

The information will be provided in aggregate form and the use of any measurement methodologies, such as quality of life scales and carer satisfaction surveys is to be determined prior to the commencement of operation of the NFC or if a new or amended measurement at the beginning of the financial year the data is to be collected.

The annual reports will inform decision making as to the 'eligible' number of patients payable for each NFC. Other factors to be considered in determining appropriate allocations will include improving patient access and maintaining sufficient throughput at existing NFC units to ensure maintenance of skills and efficiency in service provision.

When sites are approved by AHMAC through CTEPC, the NFC Reference Group will consult with new sites to agree performance criteria as the basis for reporting and action plans.

A pro forma for the above information is at Appendix 3.

4.7 PATIENT AND FAMILY QUESTIONNAIRE

NFC patients and/or their families will be invited to complete a questionnaire to give their views on how they felt their care, or the care of a family member, was managed under the NFC Program.

The questionnaire is provided to patients and/or their families on discharge from the NFC Program and can be completed by a parent, a child and/or the whole family. Participation is voluntary. Responses are submitted to the NFC Secretariat and all responses and comments will be anonymous.

The responses are used by the NFC Reference Group to identify opportunities for process improvement and program development. The questionnaire is not used for rating or assessing individual program sites or clinicians.

The NFC secretariat will analyse and report on the questionnaire responses annually (on a calendar year basis) to the NFC Reference Group.

SECTION 5 – ESTABLISHMENT OF A NEW NATIONALLY FUNDED CENTRE (NFC)

The flow chart in Appendix 4 provides a summary of the nomination, assessment and site selection process for a new NFC. The key steps are as follows:

- nomination of a proposed technology;
- approval by AHMAC through CTEPC to undertake an assessment of the technology for NFC status;
- detailed submission provided by nominating jurisdiction;
- assessment of the technology;
- recommendation to AHMAC through CTEPC by the NFC Reference Group; and
- consideration of eligibility and other factors in determining the number and location of the NFC sites.

In exceptional circumstances, AHMAC may make specific requests for assessments of procedures for NFC status and/or a review of a current program and provide funding.

If NFC status for the technology is approved by AHMAC through CTEPC, expressions of interest for a site(s) will be called from jurisdictions.

5.1 NOMINATION OF A PROPOSED TECHNOLOGY – SUMMARY SUBMISSION

There is one annual cut off date for nominations of a proposed new NFC. Nominations must be received by the NFC Secretariat before close of business on the second Monday of December.

The Australian Government, a State or Territory jurisdiction can forward submissions to the NFC Reference Group nominating a technology for NFC status. Joint jurisdictional nominations are encouraged but not mandatory. Submissions will **not** be received from individual clinicians or centres.

The intention of the nomination is to seek approval for an assessment of the technology to be undertaken for consideration of NFC status. No consideration is given to site numbers or the potential location of sites at this stage.

The submission nominating a new technology should be no more than five pages and include the following information:

- description and classification of the new technology;
- clinical indication / disease / condition for treatment by proposed technology / clinical practice;

- international and national practice and the current status (i.e. emerging, growing, declining) of the technology internationally;
- evidence of clinical and cost effectiveness;
- benefits of the technology;
- estimation of the likely level of national demand; and
- evidence of the requirement for the technology to be planned and delivered on a nationally consistent basis.

A pro forma outlining these requirements is provided at Appendix 5.

Upon receiving a nomination the NFC Reference Group will:

- review the documentation;
- comment on the nomination;
- make a recommendation to AHMAC, through CTEPC, to either progress the assessment of the technology for consideration as a new NFC, or to not support the undertaking of an assessment;
- provide information to contribute to assessment of the technology (if applicable); and,
- provide information on the treatments that could be compared with, or substitute for, the technology / clinical practice proposed to be a NFC.

If information is provided indicating that the technology is not appropriate for an assessment and there is agreement from the nominating jurisdiction(s), the nomination will not be sent to AHMAC through CTEPC. Reasons for the decision will be made available.

If the NFC Reference Group believes that the technology is not appropriate for assessment, and the nominating jurisdiction(s) still wants the nomination to be forwarded to AHMAC through CTEPC, it will be submitted with the majority recommendation, noting the dissenting views.

The NFC Secretariat will prepare and forward a proposal to AHMAC through CTEPC based on the recommendations of the NFC Reference Group.

Jurisdictions may indicate a dissenting view to the NFC Reference Group recommendation at the AHMAC meeting.

5.2 APPROVAL TO ASSESS – DETAILED SUBMISSION

If AHMAC, through CTEPC, approves a recommendation to assess a proposed new technology, the nominating jurisdiction(s) is/will be required to prepare a full and comprehensive submission. This detailed submission will be provided to the assessing body, once appointed.

The pro forma for the detailed submission and information required is provided in Appendix 6.

Costing details need to be provided in accordance with the costing pro forma at Appendix 2.

In providing this information, jurisdictions should be mindful of the fact that where numbers are small, there is the potential for patients to be identifiable. The need for patient privacy may be more acute.

The nominating jurisdiction(s) is/are responsible for ensuring that the data provided in the detailed submission is accurate. The jurisdiction(s) should complete the detailed submission within three months of receiving formal advice from the NFC Secretariat of AHMAC's approval to proceed with the assessment. The detailed submission should be forwarded to the NFC Secretariat.

5.3 ASSESSMENT PROCESS

The NFC Reference Group will nominate three of its members to be a Project Management Group who will manage the selection process to engage an assessing body and will oversee the assessment process. The NFC Secretariat will provide administrative support and act as liaison between the consultant and the Project Management Group.

The Project Management Group will act on behalf of the NFC Reference Group and ensure the reference group is regularly briefed on progress. Project Management Group members are required to declare to the NFC Reference Group in writing if they have any potential conflicts of interest in relation to their role on a Project Management Group.

The NFC Project Management Group, on behalf of the NFC Reference Group will contract an assessing body to undertake a comprehensive health technology assessment and to consider and advise on the suitability of the technology for inclusion in the NFC Program.

The NFC Reference Group will not necessarily undertake a full procurement process for required work but in making the decision on the assessing body, will take into account expertise / ability, track record, quality of the work, value for money, and timeframes.

The NFC Reference Group will negotiate with the assessing body and agree a work plan for the assessment, including the structure of the process, roles, responsibilities, reporting, timelines and consultation. These negotiations should ensure that the scope of the work is clearly understood by the assessing body. The assessing body will also need to give consideration to and manage any conflicts of interest.

The purpose of an assessment is to recommend (or not) NFC status for the nominated new technology and, if recommended for NFC status, how many sites should be established and what criteria should be used to select the site(s). No consideration is given to the potential location of sites at this stage. Site selection is a separate process undertaken after the technology has been approved for NFC status by AHMAC.

The NFC Secretariat will provide the assessing body with a copy of the detailed submission(s) and a copy of this NFC Guidance document.

The assessing body undertaking the HTA will comprise evaluators with significant experience in this work. It will include personnel with expertise in the clinical specialty, health services planning, health economics and technology assessment. It is critical that any conflicts of interest are disclosed before parties are involved in this process.

Given the specialised nature of technologies proposed for NFC status, input from international experts to assist in independent assessment is strongly encouraged. Experts with recent and relevant offshore experience (within the last 5 years) would be suitable in most cases, however for more contentious assessments, an expert who is living and working overseas should be engaged.

The assessing body will use the criteria listed in Appendix 7 to assess the proposed NFC.

Key considerations of the assessing body are:

- Will inclusion of the technology in the NFC Program maintain or improve quality of care and equity of access for Australian patients?
- Is there a need to concentrate the service in order to achieve quality outcomes?
- Where there is a level of demand that can be met by just one to two centres nationally, how is this balanced with the need to optimise access?

The assessing body will also consider particular issues that may be appropriate for implementation and establishment of the NFC including, but not limited to, criteria for site selection, monitoring and evaluation, clear criteria for patient selection, development of protocols and governance.

The assessing body may require out of session discussions with the NFC Reference Group to further refine the scope after commencing the HTA.

The recommendations of the HTA report must only reflect the agreed scope of the assessment. Comments regarding issues outside the stated scope of the assessment may be included in the body of the final report.

The process for finalising and commenting on the HTA report will be as follows:

- a draft report with recommendations is to be referred to NFC Reference Group for comment and forwarding to all jurisdictions and sites for comment including comments on factual information and accuracy;
- the NFC Reference Group refers comments from jurisdictions to the assessing body to enable the assessing body to progress the report;
- the assessing body will consider the comments and provide jurisdictions with a formal response to their comments;
- a final draft report incorporating (or not) the comments received from jurisdictions is provided for a final check by jurisdictions;
- the assessing body finalises the report and formally refers it to the NFC Reference Group.

5.4 APPROVAL OF NFC STATUS

The final report following completion of a HTA will include recommendations to the NFC Reference Group on the suitability or unsuitability of the technology for NFC status. If the technology is recommended for NFC status, the recommendations will also include whether there should be one or more than one NFC site and the criteria for selecting the site or sites.

Based on the recommendations of the assessing body and consideration of other factors as appropriate, the NFC Reference Group will provide a recommendation (including any dissenting view(s)) to AHMAC through CTEPC regarding the suitability or unsuitability of the technology for NFC status.

If NFC status is approved, the NFC Reference Group will proceed with site selection.

5.5 SITE SELECTION – EXPRESSIONS OF INTEREST AND SITE ASSESSMENT

Expressions of interest:

Once the technology has been approved by AHMAC for NFC status, expressions of interest (EOI) to host a site will be called from one or more jurisdictions. It is at this stage that any conflicts of interest must be declared by NFC Reference Group members.

A copy of the assessment of the technology will be provided to potential sites as background for the EOI.

Areas to be addressed in the EOI for site nomination are:

- demonstrated experience and expertise in providing the technology, including reference to the team as a whole, and individuals within the team;
- whether the institution is prepared to accept patients for this technology from anywhere in Australia;
- availability of all requirements and support services to provide a complete service;
- patient care including approach to service delivery, criteria for patient selection onto the program and interaction with referrers;
- quality and safety data collection and evaluation;
- identification of risk management strategies to mitigate against potential risks to the viability and operations of the service; and
- implementation and establishment strategies.

For further information about what is required, refer to the pro forma in Appendix 2 and Appendix 8. Both pro formas must be completed for all EOIs.

Site Assessment:

The NFC Reference Group will recommend to AHMAC, through CTEPC, one or more NFC site taking into consideration the following factors:

- expertise at the centre should be at such a level that outcomes for the technology in question, or (if its use has not yet commenced) closely related technologies, compare favourably with those reported internationally;
- the centre should be able to provide the technology at the most cost effective price at which satisfactory outcomes can be achieved;
- access should not be unduly hindered by transport difficulties (including access for persons requiring treatment and individuals who are acutely unwell, consideration of follow up treatment requirements, and access to organs where applicable);
- there should be no institutional impediments to access;
- the institution should agree to relevant data collection, monitoring quality and safety and evaluation of the technology;
- the institution should have the capacity to undertake associated research and development;
- any auxiliary associated services required (such as diagnostic and support services, parent accommodation in the case of paediatric services) should be available at a high standard and reasonable cost;
- workforce availability and retention;
- identification of risk, and management strategies to mitigate against the risk; and
- implementation and establishment issues/contingencies.

The assessing body may be asked to provide some further advice in regard to site selection if:

- there are queries about a proposed site;
- a greater number of sites nominate to provide the technology than recommended by the assessing body: and / or
- the NFC Reference Group can not reach agreement on the site(s).

The NFC Reference Group will confirm and finalise funding requirements with the host jurisdiction(s). The NFC Reference Group may choose to engage an independent consultant for a more detailed costing study. The NFC Secretariat will then calculate the financial implications for all jurisdictions.

The NFC Reference Group will then make a recommendation to AHMAC through CTEPC on the site or sites and a financial proposal including the price for the new procedure and the estimated activity for the first year.

5.6 ESTABLISHMENT OF THE NFC

Once the site or sites have been approved by AHMAC, through CTEPC, the NFC Reference Group, on behalf of AHMAC, will formally notify:

- the relevant State or Territory health authorities;
- all other jurisdictions;
- assessing bodies; and
- other relevant bodies.

The proposal to AHMAC will include any special conditions for the NFC and the appropriate agreed date for review (usually three years after approval). It will also include arrangements for data to be collected for annual reporting such as evaluation of health, safety and quality outcomes, plus equity access and resource utilisation. The data collection and reporting requirements will be developed in consultation with sites and a pro forma will be provided for sites annually to satisfy the agreed reporting requirements. Jurisdictions will be responsible for ensuring that the data provided as part of the annual review of NFC sites is accurate.

New NFC sites commence operations on 1 July of the year following the decision, in line with the budgetary process.

There is an expectation that a technology funded under the NFC Program is only provided through the approved NFC sites. States and Territories are expected to discourage the proliferation of the NFC technology across other health services within their jurisdictions. It should be noted that a State or Territory cannot renege on the funding of their share of the NFC Program, even if they elect to provide the procedure at a site other than an approved NFC site.

SECTION 6 – REVIEWS OF EXISTING NATIONALLY FUNDED CENTRES (NFCs)

6.1 TIMING OF REVIEWS

The NFC Reference Group will recommend to AHMAC through CTEPC the commissioning of a review of a new NFC three years after its initial establishment.

In general, future reviews will also be every three years however the NFC Reference Group may request a review be undertaken prior to the three years or more than three years, up to a maximum of five years. The reviews will include service delivery issues, costs and funding.

In exceptional circumstances, AHMAC may make specific requests for assessments of procedures for NFC status and/or a review of a current program and provide funding.

The NFC Reference Group may request a review be undertaken before the three-year review process in the following circumstances:

- where a review outcome or approval for a new NFC includes a recommendation for an earlier review;
- where a review outcome recommends an expansion of the number of NFC sites;
- where a change in clinical practice has resulted in a significant cost increase;
- where a change in clinical practice has resulted in the NFC no longer being required or has otherwise impacted on the scope of the services provided;
- when a technology changes more quickly than anticipated; or
- when an unforeseen issue arises with an existing NFC.

The NFC Reference Group may request a review be undertaken after an extended period, up to a maximum of five years, in one or more of the following circumstances:

- where there is a view that the technology / clinical practice will not change for the extended period;
- where the quality of the information being provided in the annual reports is satisfactory to monitor the NFC between reviews;
- where the recommendations from the most recent review support an extended period between reviews,
- where it will achieve a reduction in administrative costs without compromising patient safety.

A NFC site can request a review of the cost of a procedure prior to the three-year review process where emerging technology has resulted in significant modifications to the treatment being provided. The request should be made to the NFC Reference Group through the jurisdictional representative. A price review will be considered by the NFC Reference Group in the first instance, with expert advice to be sought as required. If a price review has been approved by the NFC Reference Group, and subsequently by AHMAC through CTEPC, the outcome will be implemented as an adjustment to the next NFC annual budget.

6.2 ADMINISTERING REVIEWS

The NFC Reference Group will engage a consultant / agency to undertake a review of an existing NFC.

The NFC Reference Group may not necessarily undertake a full procurement process to engage a consultant with the decision to be based on the scope of the review and taking into account the reviewing body's expertise, ability, track record and quality of work, as well as value for money and timeframes.

The NFC Reference Group will nominate three of its members to be a Project Management Group who will manage the selection process to engage a reviewing body and will oversee the review process. The NFC Secretariat will provide administrative support and act as liaison between the consultant and the Project Management Group.

The Project Management Group will act on behalf of the NFC Reference Group and ensure the reference group is regularly briefed on progress. Project Management Group members are required to declare to the NFC Reference Group in writing if they have any potential conflicts of interest in relation to their role on a Project Management Group.

The NFC Project Management Group, on behalf of the NFC Reference Group will contract a reviewing body to undertake a comprehensive review and to consider and advise on the suitability of the technology for continuation within the NFC Program.

The NFC Reference Group will negotiate with the reviewing body and agree a work plan for the review, including the structure of the process, roles, responsibilities, reporting, timelines and consultation. These negotiations should ensure that the scope of the work is clearly understood by the reviewing body. The reviewing body will also need to give consideration to and manage any conflicts of interest.

The NFC Secretariat will request information from the existing NFCs and forward this information to the reviewing body. In providing this information, jurisdictions should be mindful of the fact that where numbers are small, there is the potential for patients to be identifiable. The need for patient privacy may be more acute.

Jurisdictions are also responsible for ensuring that the data provided for the review process is accurate.

The reviewing body will comprise evaluators with significant experience in this work. It will include personnel with expertise in the clinical specialty, health services planning, health economics and health technology assessment. It is critical that any conflicts of interest are disclosed before parties are involved in this process.

Given the specialised nature NFC technologies, input from international experts is strongly encouraged to assist in an independent review. Experts with recent and relevant offshore experience (within the last 5 years) would be suitable in most cases, however for more contentious reviews, an expert who is living and working overseas should be engaged.

The reviewing body will use the criteria listed in Appendix 9 to assess the proposed NFC.

6.3 CRITERIA FOR REVIEW

Criteria to be considered as part of a review are listed in Appendix 9, these include:

- access to the NFC (including clear criteria for patient selection and, where they do not exist, a recommendation that such criteria be developed);
- health outcomes;
- model of care and service delivery;
- quality and safety;
- teaching, training and research;
- changes to clinical practice;
- service demand;
- cost; and
- risk management.

The need for, and benefits of, continued service concentration will be considered taking into account the above information and including, but not limited to:

- health outcomes achieved to date;
- new evidence on effectiveness of the existing clinical practice / technology and development of existing comparator treatments;
- estimates of the national demand for the technology taking into account international practice;
- equity of access to the clinical practice / technology;
- cost.

Issues such as optimal throughput and critical mass to determine the number of sites and the point at which additional of fewer sites are required may also need to be addressed.

6.4 REVIEW OUTCOMES

The possible recommendations resulting from a review could be to:

- continue the existing activities of the NFC at the same, reduced or increased level for a further defined period with a further review to be conducted at the end of the period;
- decrease the number of NFC sites providing the service;
- increase the number of NFC sites providing the service;
- withdraw NFC status effective by 30 June in the next calendar year from the date of the decision.

As part of a recommendation to continue existing activities of the NFC the following recommendations may also be made:

- address and rectify issues identified by the reviewing body, and / or
- modify the scope of services and care provided by the NFC to meet current clinical and service requirements.

A recommendation may be made to AHMAC through CTEPC to increase the number of NFC providers if it is shown that:

- satisfactory health and cost-effectiveness outcomes have been achieved;
- the existing site or sites do not have the capacity to meet the needs of the Australian population for the foreseeable future;
- the combined national and international demand justify expansion;
- the cost effectiveness of an additional site or sites is similar to that of the first site;
- establishment of an additional site or sites will not adversely affect health outcomes; and
- establishment of an additional site or sites will not adversely affect equity of access.

A balance has to be reached between the need to ensure equitable access for all to the service and the need to ensure that expansion of the number of NFC providers does not result in significant inefficiencies or dilution of expertise. If it is agreed that an expansion of the number of NFC sites is appropriate, then agreement will be reached on the timing of a further review.

The process for finalising and commenting on the review report will be as follows:

- a final draft with recommendations is to be referred to NFC Reference Group for comment;
- the NFC Reference Group forwards a copy to all jurisdictions and sites for comment, including comments on factual information and accuracy;
- the NFC Reference Group collates the comments and refers them to the reviewing body to enable the reviewing body to finalise their report;
- the reviewing body considers the comments provided, and provides jurisdictions with a formal response to their comments;
- the reviewing body finalises their report and formally refers it to the NFC Reference Group.

SECTION 7 – CESSATION OF A NATIONALLY FUNDED CENTRE (NFC)

At some point in the provision of a specific NFC Program, agreement may be reached by AHMAC that NFC status is no longer appropriate.

This point may be reached when:

- there is no longer any need for a NFC as the technology is provided in the majority of jurisdictions; or
- the technology has been superseded by another clinical practice.

If at this point some States and/or Territories are still not providing the service, then the usual arrangements for State, Territories and/or Australian Government funding of cross border services will apply.

Arrangements will be made to continue a centralised data collection for the service if appropriate.

Where AHMAC approves the withdrawal of NFC status, the affected site or sites will cease as a NFC effective by 30 June in the next calendar year.

ROLES AND RESPONSIBILITIES NATIONALLY FUNDED CENTRES (NFC) PROGRAM

Assessing Body

The assessing body is an independent consultant organisation engaged by the NFC Reference Group, on behalf of AHMAC, to undertake assessments for proposed technologies / clinical practices as required. The assessing body evaluates health technologies and highly specialised services examining criteria such as safety, efficiency, effectiveness, cost, equity of access and social impact.

Australian Government

The role of the Australian Government is to participate in NFC processes, including the health technology assessment and NFC procedure review processes, and as a member of the NFC Reference Group.

Australian Health Ministers' Advisory Council

The Australian Health Ministers' Conference (AHMC) assigned oversight of all aspects of the NFC Program and associated policy to the Australian Health Minister's Advisory Council (AHMAC). This includes considering all recommendations forwarded to it by the NFC Reference Group, making decisions on recommendations and adjudicating on matters where the NFC Reference Group is unable to make a recommendation. The NFC Reference Group reports to AHMAC through the Clinical, Technical and Ethical Principal Committee (CTEPC).

For more information about AHMAC, refer to the AHMAC website at:

<http://www.ahmac.gov.au/site/membership.aspx>.

Australian Health Ministers' Conference (AHMC)

At the June 1990 AHMC, Ministers endorsed a national policy for public sector provision of high cost, highly specialised clinical practices and technologies with limited demand. This is the Nationally Funded Centres (NFC) Program. The AHMC subsequently assigned oversight of all aspects of the NFC Program and associated policy to the Australian Health Minister's Advisory Council (AHMAC).

Clinical, Technical and Ethical Principal Committee

The NFC Reference Group reports to AHMAC through the Clinical, Technical and Ethical Principal Committee (CTEPC). For more information about the CTEPC refer to the Principal Committees link on the AHMAC website at:

<http://www.ahmac.gov.au/site/membership.aspx>.

Health Policy Advisory Committee on Technology (HealthPACT)

A nominee of HealthPACT can attend NFC Reference Group meetings as an observer. For more information about HealthPACT refer to their website at:

<http://www.health.gov.au/internet/horizon/publishing.nsf/Content/healthpact-2>.

Nationally Funded Centres (NFC) Reference Group

The NFC Reference Group is established by AHMAC and comprises of a representative from the Australian Government and each State and Territory.

The NFC Reference Group is responsible for:

- the planning and management of the NFC Program;
- ensuring submissions for new NFCs are assessed (subsequent to approval by AHMAC through CTEPC);
- undertaking the review of existing NFCs every three years, or at other times as approved;
- making recommendations to AHMAC through CTEPC regarding proposals for new technologies;
- making recommendations to AHMAC through CTEPC regarding the outcome of reviews of existing NFCs;
- determining the annual operating budgets for approved NFCs and for the general administration of the NFC Program; and
- developing and maintaining interfaces with relevant bodies including HealthPACT and the Australian Organ and Tissue Authority in order to maximise effective consideration of health technology issues and avoid duplication of effort.

The NFC Reference Group reports to AHMAC through the Clinical, Technical and Ethical Principal Committee (CTEPC) and meets as required.

The NFC Reference Group coordinates an annual Clinicians' Workshop where it meets with clinicians from the NFC sites to discuss current issues and process improvements. The outcomes of these annual workshops (held in February each year) influence the NFC Reference Group's work plan for the next financial year.

A nominee of HealthPACT can attend NFC Reference Group meetings as observers.

Nationally Funded Centres (NFC) Reference Group Secretariat

Administration of the NFC Program is undertaken by a host jurisdiction nominated by AHMAC. The host jurisdiction establishes a NFC Reference Group Secretariat (the NFC Secretariat) for this purpose.

The NFC Secretariat is responsible for providing the NFC Reference Group with administrative support for:

- NFC assessments and reviews;
- the annual budget process, including the collection and analysis of data;
- routine reviews and updates of the Guidance document for the NFC Program in consultation with the Australian Government, the States, Territories and NFC units;
- all NFC Reference Group meetings;
- the annual clinician's workshop and NFC Reference Group meeting to be held in February each year; and
- a national website for the NFC Program.

Project Management Group

The NFC Reference Group will nominate three of its members to be a Project Management Group (PMG) who will manage the selection process to engage an assessing/reviewing body and will oversee the assessment/review process. The NFC Secretariat will provide administrative support and act as liaison between the appointed consultants undertaking the assessment/review and the PMG.

The PMG will act on behalf of the NFC Reference Group and ensure the reference group is regularly briefed on progress. PMG members are required to declare to the NFC Reference Group in writing if they have any potential conflicts of interest in relation to their role on a PMG.

The role of the PMG will include:

- Evaluation of tenders against the established Evaluation Criteria.
- Preparation of a written report on the evaluation including findings, recommendation of successful tender and associated costs.
- Project management of the assessment/review from commencement of the consultancy to final report stage.
- Agree a work plan with the successful tender.
- Assess and agree the achievement of milestones for approval of progress payments to consultants.
- Accompany the consultants to site visits (nominate one PMG member per visit).
- Ensure regular reporting to the NFC Reference Group on the progress of the assessment/review.

Reviewing Body

The reviewing body is an independent consultant organisation engaged by the NFC Reference Group, on behalf of AHMAC, to review existing NFCs based on criteria such as safety, efficiency, effectiveness, cost, equity of access and social impact, and make recommendations on their continuation, expansion, cessation and/or pricing as required.

State and Territory Health Departments

The role of the State and Territory health departments is to:

- nominate a jurisdictional representative to be a member of the NFC Reference Group;
- participate in NFC processes, including the health technology assessment and NFC procedure review processes;
- host designated NFC services in accordance with the agreed NFC Guidance document;
- cooperate with all other States and Territories in the provision of NFC services, regardless of whether they are host or non host States and Territories; and
- contribute to the NFC budget.

**COSTING PRO FORMA
NATIONALLY FUNDED CENTRES (NFC) PROGRAM**

The following costing data is to be provided when:

- *nominating jurisdictions provide detailed submissions to support consideration of a new NFC (refer section 5.2 and Appendix 6); or*
- *jurisdictions provide information to support their expression of interest to host a site following the assessment of a technology for NFC status (refer section 5.5 and Appendix 8); or*
- *an existing NFC is being reviewed (refer section 6 and Appendix 9); or*
- *a jurisdiction is seeking a change in the NFC price per procedure after establishment but before the next scheduled review (refer section 4.4).*

NFC or Proposed NFC:

Health Service/Hospital:

Chief Executive of Health Service/Hospital

Name:

Signature:

Date:

Jurisdictional Endorsement

Name/Title:.....

Signature :.....

Date:

Jurisdictional Contact

Name/Title:.....

Telephone No:..... Facsimile No:

E-mail address:.....

Postal Address:

.....
.....
.....

1. Overview

This pro forma is a guide to the information and data required for an assessment or review process and provides guidance on what should be discussed with the jurisdictional representative on the NFC Reference Group from your State or Territory government department. The pro forma also outlines the methodology and the types of costs to be included for all costing submissions. The submission must be directed through your State or Territory government department for review and sign-off.

Detailed information is to be provided on:

- establishment costs, which may include, as a once off, items such as:
 - additional staff costs required for the commissioning of complex equipment;
 - the cost of start up consumables such as the range of coils required for interventional neuroradiology (INR) procedures
 - education and promotion materials and activities;
- direct and indirect operational costs for the patient care pathway;
- facility and equipment costs; and
- projected annual costs.

The NFC Program is a small program and the NFC Reference Group aims to keep it as simple as possible. The simplicity of the costing methodology and the funding model is designed to minimise the costs of administration and to establish a low compliance burden on NFC sites and host jurisdictions.

The NFC funding provided should be reasonably commensurate with costs of the NFC part of a service. While the costing methodology is designed to establish a reasonable cost for each NFC procedure, it is not a full cost recovery model. All jurisdictions will be expected to contribute some costs that relate to the NFC Program (e.g. initial assessments undertaken in home jurisdictions and paid for by those jurisdictions).

The NFC Reference Group will review the NFC costing methodologies and funding model every three years.

If the projected costs are based upon historical data, this needs to be clearly identified.

2. Care pathway costs

Care pathway costs incorporate direct patient costs for each phase of patient care including indirect patient costs and health service / hospital overheads. The costing information should reflect the mean cost per patient.

Where there is more than one patient care pathway in the NFC procedure with substantially different care elements and cost implications, separate care pathway costs should be developed. In general, funding will not be considered for different clinical pathways for an agreed procedure. However, consideration may be given to different pathways where the cost differentials are significant and the numbers involved are material. This will be considered on a case by case basis by the NFC Reference Group, along with the determination of what is deemed to be significant and what is deemed to be material.

The NFC funding provided should be reasonably commensurate with costs of the NFC part of a service. If there are multiple sites for a single procedure, in general, the NFC Program will pay the lesser price for all sites. However, the NFC Reference Group will consider variations to the 'lesser price' principle on a case by case basis where the lesser price is determined to be inadequate. The NFC Reference Group may choose to engage an independent consultant for a more detailed costing study.

A clear definition of the start and end point for the episode of care of the individual NFC procedure is required. In general the jurisdiction will pay for the patient until the patient is accepted onto the NFC Program and the NFC Program pays up to three months post discharge, after which the jurisdiction will again be responsible for the patient costs. There may be exceptions to this general scope depending on the type of procedure funded under the program.

The costs of those patients who are accepted onto the program, receive an assessment and work-up but do not proceed to the procedure stage, also need to be considered in calculating the cost per procedure. These calculations will be reviewed as part of the NFC Program review cycle and NFC sites will be asked to report annually on the number of patients accepted onto the program but who do not proceed to treatment.

2.1 Direct patient costs

This care pathway assumes that the NFC provides a procedure with post procedure care either in a high dependency or intensive care unit. In general, only costs incurred at the NFC site are to be included. However, there may be exceptions to this general rule depending on the type of procedure funded under the program and AHMAC may approve, on a case by case basis, variations to this general position.

The suggested phases of care are:

-
- acceptance for NFC treatment;
- pre treatment outpatient monitoring;
- pre treatment inpatient care;
- theatre / surgery and other procedures integral and required as part of care;
- high dependency / intensive care;
- general ward admission;
- outpatient care prior to discharge from the NFC site;
- other direct patient costs including transport and accommodation.

Where these phases do not apply for a particular NFC or some NFC patients, the care pathway should be modified, described and costed accordingly. Considerations for delineating the NFC care pathway and costs include:

- the type of treatment being undertaken at the NFC;
- components of treatment that are NFC specific or can be undertaken elsewhere;
- where the patient lives;
- the capacity and capability to provide services where the patient lives;
- whether pre treatment inpatient care is required;
- whether pre treatment outpatient monitoring can occur where the patient lives;
- whether all post treatment outpatient care can occur where the patient lives.

2.2 Indirect patient costs

Indirect patient costs are:

- NFC Program management costs - this assumes that the NFC is embedded in a health service / hospital department with costs apportioned on the basis of time spent or bed days covered by various personnel on the NFC Program; and
- Health service / hospital administration and overhead costs - these costs are generally calculated as a percentage of the direct patient care costs.

2.3 Detailed care pathway costs

Table 1 is a pro forma with individual cost elements to be considered for each phase of care. Each element needs to describe the cost measure, the basis for derivation of the costs, the quantity being costed, and the overall cost for that element. Indicative cost measures are:

- types of consultations;
- specific diagnostic tests;
- bed day cost; and
- cost per day.

The cost derivation is to describe the basis for costs and could include:

- Award rates;
- calculation of salary overheads;
- prices for pharmaceuticals, medical devices, implantables and such;
- clinical costing information;
- the amount of time for a consultation;
- the numbers of tests; and
- MBS scheduled fees.

TABLE 1: Detailed Care Pathway Costs Based on Mean Costs

	COST MEASURE (what is being measured)	COST DERIVATION (how is the cost calculated)	QUANTITY	COST
CARE PATHWAY COSTS				
1. REFERRAL TO SERVICE				
Medical and other consultations				
SUB-TOTAL REFERRAL TO SERVICE				
2. WORK-UP				
Medical consultation and review				
Nursing and Allied Health consultation				
Joint Expert Multidisciplinary Review				
Imaging Diagnostic Assessment				
Pathology Diagnostic Assessment				
Other Medical Consultations				
Supplies/consumables				
Specialist consultations and diagnostic work-up for particular NFC contingencies (please specify)				
Other (please specify)				
SUB-TOTAL WORK-UP				
3. ACCEPTANCE TO NFC PROGRAM				
Joint Expert Multidisciplinary Review				
SUB-TOTAL ACCEPTANCE ON LIST				
4. INPATIENT / OUTPATIENT PRE NFC TREATMENT MONITORING:				
Medical / Nursing Monitoring				
Allied Health Monitoring / review				
Imaging				
Pathology				
Other (please specify)				
SUB-TOTAL PRE TRANSPLANT MONITORING				
5. THEATRE / SURGERY				
Pre theatre ward care				
Theatre Salaries & Wages				
Theatre Utilisation				
Implantable Medical Devices				
Theatre Consumables				
Theatre Recovery				
Intra operative imaging / pathology				
Other (please specify)				
SUB-TOTAL THEATRE/SURGERY				
6. OTHER PROCEDURES (non surgical)				
SUB-TOTAL OTHER PROCEDURES (non surgical)				

7. HIGH DEPENDENCY UNIT / INTENSIVE CARE ADMISSION				
Bed Day Cost (including ward nursing)				
Consumables				
Medical Monitoring				
Specialist Nursing Monitoring				
Surgical Review				
Allied Health Monitoring / Review				
Nutrition & Special Supplements				
Drugs / Pharmacy				
Imaging / Pathology				
Other (please specify)				
SUB-TOTAL INTENSIVE CARE				
8. GENERAL WARD ADMISSION				
Bed Day Cost (including ward nursing)				
Consumables				
Medical Monitoring				
Specialist Nursing Monitoring				
Surgical Review				
Allied Health Monitoring / Review				
Patient Meals / Nutrition				
Drugs / Pharmacy (excluding S100)				
Imaging / Pathology				
Other (please specify)				
SUB-TOTAL WARD ADMISSION				

9. OUTPATIENT CARE PRIOR TO DISCHARGE FROM THE NFC PROGRAM				
Consumables				
Medical Monitoring				
Specialist Nursing Monitoring				
Surgical Review				
Allied Health Monitoring / Review				
Nutrition				
Drugs / Pharmacy (excluding S100)				
Imaging				
Pathology				
Other (please specify)				
SUB-TOTAL OUTPATIENT CARE PRIOR TO DISCHARGE FROM THE NFC PROGRAM				
10. OTHER DIRECT PATIENT COSTS				
Accommodation Interstate Patients / Parent / Carer				
Travel Interstate Parent / Carer				
Other expenses Interstate Patients / Parent / Carer				
Travel/Transport for patient (inc interstate)				
Ambulance				
Patient and family education				
Other (please specify)				
SUB-TOTAL OTHER DIRECT COSTS				
TOTAL DIRECT COSTS				

11. OVERHEADS / INDIRECT COSTS				
PROGRAM MANAGEMENT				
Unit Head				
Administrative / Clerical				
CNC Nurse Co-ordinator				
Other (please specify)				
SUB-TOTAL PROGRAM MANAGEMENT				
ADMINISTRATION & OVERHEADS				
Infrastructure & Other				
Fuel, Light & Power				
Depreciation				
Insurance				
Maintenance Contracts				
Motor Vehicle Costs				
Repairs & Maintenance				
Linen & Laundry				
Other (please specify)				
Health Service / Hospital Management				
Human Resource Management				
Information Technology				
Finance Department				
Supply and Materials Management				
Facilities Management				
Planning and Development				
SUB-TOTAL OTHER COSTS AND OVERHEADS				
TOTAL INDIRECT COSTS				
GRAND TOTAL DIRECT & INDIRECT COSTS				

3. Capital: facility and equipment costs

Facility and equipment costs for NFCs will not be considered by the NFC Reference Group and recommended to AHMAC unless a robust business case can be made based on the following contingencies.

3.1 *Equipment*

Costs for specialised NFC equipment may be incorporated through apportioning a depreciation allowance, on a per patient basis, taking into account the projected number of patients and life of the equipment.

In determining an appropriate depreciation allowance for equipment, proposed NFCs should consider two categories of equipment:

- (1) equipment dedicated to the proposed NFC Program and not used elsewhere in the hospital, and
- (2) equipment utilised elsewhere in the hospital but substantially required by the proposed NFC for a **minimum** of 70% of the time.

Only equipment valued at more than \$25,000 per item in terms of current purchase price or replacement cost is eligible for consideration.

The useable life for equipment to be applied in calculating depreciation rates using a simple per annum straight-line depreciation method is as follows:

Equipment	Time
Fibre optics, computer hardware and computerised equipment:	5 years
Monitors, monitoring equipment:	8 years
Therapeutic equipment:	10 years
Diagnostic equipment, analysers etc:	10 years

Justification for the NFC equipment and costs for its repair and maintenance are to be tabulated as follows in Table 2:

TABLE 2: NFC equipment

Item	Purchase price	Purchase date	% of usage for NFC	Justification	Repair cost	Maintenance	Depreciation

Large maintenance contracts for individual items of equipment should be listed individually and appended to the completed form.

At the time of establishing a new NFC, AHMAC may consider, on a case by case basis, capital support for a new approved NFC technology where that technology/clinical practice is not done anywhere else in Australia. In the event that capital funding is agreed, there will be no allowance for depreciation in annual costings.

3.2 Facilities

Facility costs may be considered if:

- there are facility enhancements specifically required for establishment of the NFC, such as specialised shielding, plumbing or electrical works; this should only be considered if these works are for areas used for a **minimum** of 70% of the time by NFC patients; and
- the numbers of patients and their use of hospital facilities justifies the inclusion of a rental payment in the NFC price.

Facility enhancements:

Information on these is to be provided as per Table 3.

TABLE 3: NFC facility enhancements

Description	Cost	Justification

Use of health service / hospital facilities:

- a) Details to be provided in relation to the use of health service or hospital facilities:
- expected bed utilisation by NFC patients;
 - the analysis to support use of this number of beds;
 - numbers of staffed and funded beds in the treatment ward locations as indicated in Table 4 (below).

TABLE 4: NFC bed utilisation

Treatment ward	NFC beds	Total beds	Total est area m ²
ICU			
High Dependency			
General Ward			
Total			

- b) In relation to the use of other facilities, details must be provided on the proposed NFC use, with the duration of NFC specific and usual use. Estimated area, and supporting analysis, also to be provided, as per Table 5.

TABLE 5: NFC facility utilisation

Facility	NFC hrs/wk	Total hrs/wk	Total est area m ²
Theatre			
Procedure room (specify)			
Treatment room			
Other (specify)			
Total			

- c) In relation to the use of health service or hospital facilities, details must be provided in relation to the estimated NFC share of facilities and proposed rental, as follows.
- Treatment wards
 - total beds
 - space equivalent (provide details)
 - Other facilities:
 - space equivalent (provide details)
 - Notional rental
 - rent/ m² per annum
 - rent per annum

4. Summary of total annual patient costs

4.1: Total cost: all patient pathways

TABLE 6: Total cost: all patient pathways

Patient Pathways	Pathway 1	Pathway 2	Pathway 3	Total Annual Patients
Annual no Patients				
Operational cost / patient				Total Operational Cost / Patient Pathways
Direct				
Indirect				
Sub Total				
Capital				Capital cost all patients / Patient Pathways
Facilities				
Equipment				
Sub-total				
Grand Total: All Patients / All Patient Pathways				

This table will need to be modified based on the numbers of patient pathways within a NFC.

4.2 Projected annual costs for the life of the NFC: three years

The annual number of patients may increase over the three years post establishment of a new NFC or before the next review of an existing NFC. Reasons for the projected increase in annual patient numbers are required.

It is anticipated that any increase would be the reason for any increase in total costs over this time. If there were associated capital costs, the mean cost per patient would decrease over time as these costs are amortised over all patients in a given year.

As previously indicated, if there are substantive changes to costs with consequent funding implications over this time, new detailed costing information should be provided to the NFC Reference Group with the annual report.

The establishment costs of the new NFC also need to be considered, as the costs may be higher in the first year of operation. For example, the staffing costs of commissioning equipment are not able to be attributed directly to patient care.

TABLE 7: Projected NFC costs

	Year One	Year Two	Year Three
Patient Nos all pathways			
Cost / Patient all pathways			

**20XX-XX ANNUAL STATISTICAL RETURN AND ANNUAL REPORT
AND
20XX-XX ACTIVITY PLAN
NATIONALLY FUNDED CENTRES (NFC) PROGRAM**

This is to be completed annually and forwarded to the NFC Reference Group via the NFC Secretariat by the 10th working day after 1 July of each year.

Name of NFC: _____

State / Territory: _____

Health Service / Hospital: _____

1. Summary information of patient numbers

TABLE 1.1 New referrals during 20XX-XX

State or Territory of patient's residence	New referrals	Accepted	Not accepted
NSW			
VIC			
QLD			
WA			
SA			
TAS			
ACT			
NT			
Overseas (advise country), refer section 3 of NFC Guidance document			
TOTAL			

* Patients may be actively undergoing assessment to determine whether suitable for acceptance on waiting list.

TABLE 1.2: Status of 20XX-XX patients*

State or territory of patient residence	Awaiting Treatment		Treated	
	Accepted this year A	Accepted previous year(s) B	Accepted this year C	Accepted previous year(s) D
NSW				
VIC				
QLD				
WA				
SA				
TAS				
ACT				
NT				
Overseas (advise country) Refer section 3 of the NFC Guidance document				
TOTAL				

* All patients to be identified for the 20XX-XX reporting year irrespective of awaiting treatment, treated or treatment outcome. This should also include death while awaiting treatment and post treatment.

TABLE 1.3: Discharges from NFC in 20XX-XX*

State or Territory	Patients accepted that do not proceed to treatment		Patients accepted and treated that do not proceed to discharge	Patients accepted, treated and discharged
	Number exiting while awaiting treatment due to death	Number exiting while awaiting treatment due to causes other than death	Number of treated patients exiting before discharge from the NFC	Number of patients discharged from the NFC (i.e. exiting at three months post discharge from hospital)
NSW				
VIC				
QLD				
WA				
SA				
TAS				
ACT				
NT				
SA				
Overseas (advise country)				
TOTAL				

* Discharge is at the point where the ongoing care of the patient is no longer provided by the NFC.

TABLE 1.4: Types of patient outcomes in 20XX-XX*

Type	No. of patient outcomes
Patients with expected care pathway and clinical progress	
Patients with complicated care pathway and clinical progress	
Death post treatment	
TOTAL	

* The total number of patients should equal the sum of patients in columns C + D in Table 1.2.

2. Quality measures – 20XX-XX

Provide information on the patient outcomes, and clinical quality and safety indicators for the technology for the year.

2.1 Did any catastrophic adverse clinical events occur during the year (events or patterns of events which had significant implications for the patient and or/the service). YES / NO

If yes, details:

2.2 Were there any unplanned readmissions to intensive care during the year? YES / NO

If yes, details:

2.3 Were there any readmissions post discharge during the year? YES / NO

If yes, details:

2.4 Quality of Life (measurement used to collect information as agreed as per Section 4.6 of the NFC Guidance document).

Details:

2.5 Patient/family/carer satisfaction* (measurement used to collect information as agreed as per Section 4.6 of the NFC Guidance document).

Details:

2.6 Patient and transplant survival figures:

Period of analysis: _____

	Patient	Transplant
One year from treatment		
Five years from treatment		

3. Update on status of technology

3.1 An update of the status of use of the technology and associated patient outcomes in international jurisdictions.

Details:

3.2 Any changes in the initial estimation of demand for the service and reason for it.

Details:

3.3 Has there been significant modifications to the treatment being provided by the NFC if so provide evidence along with the cost implications and evidence to support these modifications.

Details:

4. Cost measurement

If there have been significant modifications to the treatment being provided by the NFC which have cost implications and an associated funding change please provide a revised costing pro forma (refer Appendix 2 of the NFC Guidance document (September 2011) available at www.nfc.sa.gov.au.)

5. Progress on the pancreas transplant NFC program review recommendations

Review recommendation 1 -

Comments from NFC site:

Review recommendation 2 -

Comments from NFC site:

6. ACTIVITY PLAN FOR 20XX-XX

6.1 Anticipated demand.

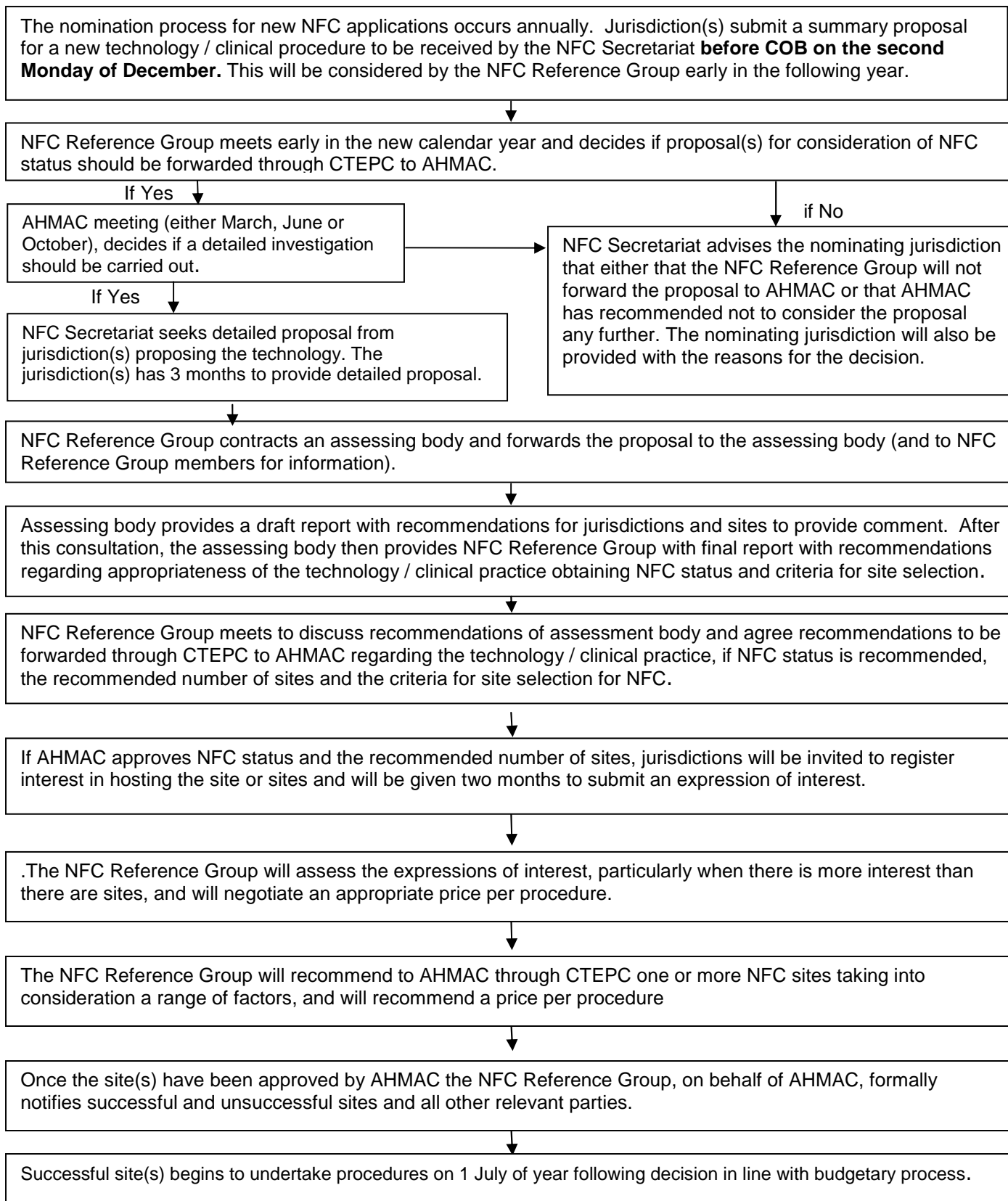
Estimated number of procedures to be performed in this coming year:

6.2 Equitable access is a foundation principle for the NFC Program. Does your service intend to undertake and activities during the year, such as outreach services, which will broaden the referral base for the service?

6.3 What actions are planned relating to staff training, staff development and sustainability?

6.4 Are there any expected changes to the nature of service delivery? Are you aware of emerging clinical or technology based issues which may affect the cohort for this service and impact on projected cases for the coming year?

**PROPOSAL/SUBMISSION/APPROVAL FLOW CHART FOR A NEW NFC
NATIONALLY FUNDED CENTRES (NFC) PROGRAM**



NATIONALLY FUNDED CENTRES (NFC) PROGRAM NOMINATION SUMMARY PRO FORMA FOR NEW NFC

This pro forma is to be used by jurisdiction(s) seeking to nominate a new NFC procedure for consideration of NFC status. For detail on the criteria required to be considered as a NFC refer to section 3 of the NFC Guidance document.

Name of technology / procedure:

- Please specify.

Nature of the technology and clinical need:

Description and classification of new technology

- Describe the technology and its application.
- Specify whether this is either a new technology; or a substitute or replacement for an existing technology.

Clinical indication / disease / condition for treatment by proposed technology/clinical practice

- Specify the condition(s) which will be treated by the technology.
- Provide information on their incidence and prevalence of these conditions in Australia.

International and national practice

- Describe the extent to which the proposed technology is in practice, internationally, and in Australia, including up to date detail of the status (that is, is it emerging, developing, being superseded or otherwise replaced or challenged).
- Include an indication of the current utilisation of the technology and distribution of the service(s).

Evidence of clinical and cost effectiveness

- Provide an overview of clinical and cost effectiveness citing key articles and/ or findings from health technology assessment.

Benefits of the technology

- Discuss the likely benefits of this technology, including:
 - a description of existing technologies / procedures that this would replace; and
 - a description of existing technologies / procedures that this would enhance.

Estimate of likely level of national demand

- Provide an indication of the basis of the catchment population by age and distribution.

Requirement to be planned and delivered on a nationally consistent basis

- Provide evidence of the requirement for the new technology to be planned and delivered on a nationally consistent basis.

DETAILED SUBMISSION PRO FORMA FOR NEW NFC NATIONALLY FUNDED CENTRES (NFC) PROGRAM

This pro forma is to be used by relevant jurisdiction(s) to provide required detailed information to assist in a full assessment by the appointed assessing body, and to be provided to the NFC Reference Group via the NFC Secretariat.

The elements to be addressed in the submission for a technology / clinical practice to be a NFC are detailed below. The source and level of evidence and information should be referenced.

Name of technology / procedure:

- Please specify.

Nature of the technology and clinical need

Description and classification of new technology

- Describe the technology and its application.
- Specify whether this is either a new technology; or a substitute or replacement for an existing technology.

Clinical indication / disease / condition for treatment by proposed technology/clinical practice

- Specify the condition(s) which will be treated by the technology.
- Provide information on the incidence and prevalence of these conditions in Australia.

Patient population(s) and projected demand for proposed technology

- Describe the demographic characteristics of the patient population(s) with the clinical condition.
- Detail the factors to be taken into account when considering patient selection and clear criteria for patient selection onto the program.
- Provide information on the predicted number of patients per annum who may benefit from the technology and potential changes in the number of patients who may benefit within the next 5 to 10 years.

Health outcomes for new technology

- What health outcomes will be achieved?
- How could the health outcomes be measured?
- Over what time frame will these outcomes occur?

Use of new technology

- Describe the extent to which the proposed technology is in practice, internationally, and in Australia, including up to date detail of the status (that is, is it emerging, developing, being superseded or otherwise replaced or challenged).

Comparison with existing approach(es) to clinical intervention

- What existing technology(s) is/are used for the clinical condition?
- Describe key differences in the indications, contra-indications, cautions, warnings and adverse effects between existing and proposed technologies.

Ethical issues

- Are there ethical issues to be considered in establishment of the technology / practice.

Safety and clinical effectiveness

Regulatory approval of new technology

- Provide evidence of approval and approval date for the technology for use in Australia for the specified clinical problem(s) for service provision (as opposed to approval for a trial) by the Therapeutic Goods Administration or other regulatory agencies as indicated.

Evidence of safety of new technology

- Provide evidence regarding safety associated with the use of the technology for the proposed clinical indication.
- Provide evidence on the nature and incidence of side effects, contra-indications, cautions, warnings and adverse effects for technology and the proposed indication, and source of this information.

Evidence of clinical effectiveness of new technology

- Summarise the evidence, outlining key aspects, for clinical effectiveness of the technology for the specified clinical problem(s).
- Identify and summarise scope, methodology and outcomes of health technology assessment undertaken for the technology by other agencies.
- Identify and summarise clinical guidelines and / or guidance on use of the technology / practice from agencies and professional bodies.
- Identify and summarise evidence and / or practice relating to quality outcomes and throughput for an organisation and / or clinical team and / or individual provider.
- Identify and describe any particular issues from the evidence about this technology / clinical practice that may influence its implementation in the public sector.

Service delivery

Model of care and service delivery

- Provide information on the following:
 - service scope and continuum of care;
 - workforce, including information on the multidisciplinary team required, training, support and succession planning and backup;
 - clinical infrastructure;
 - specialised equipment requirements;
 - facilities (bed - including special and general wards - and NFC specific establishment requirements);
 - relationship with, and provision of information to, referring practitioners;
 - outreach services in other jurisdictions;
 - teaching and training requirements;
 - current and proposed research; and
 - collaboration with international centres.

Financial implications

Cost and budget

- To be completed in the pro forma as at Appendix 2 – Costing pro forma.

Evidence of cost effectiveness of new technology

- Summarise evidence from journals, health technology assessment and other analyses, outlining key aspects for cost effectiveness of the technology for the specified clinical problem(s).

Synthesis of Evidence and Information supporting service concentration

National demand

- Provide evidence on the desirable patient throughput for an operator or team.
- Comment on whether the technology is rapidly evolving to the extent that a limited number of teams are needed to keep up with developments.
- Is there a requirement for further evaluation to determine its place in clinical practice before wider use in Australia would be appropriate?
- Information on experience and success in other jurisdictions.

Workforce

- What factors influence the development of expertise in this technology?
- Does the service involve complex multidisciplinary team work for which only a few centres could provide the full range of skills required, and the number of centres able to provide such teams could not readily be increased by training programs.
- Is expertise to provide the service scarce and not able to be readily diffused by training programs.

Clinical infrastructure

- Associated clinical infrastructure such as intensive care, operating theatre, imaging, pathology, outpatients and such.
- Specialised clinical infrastructure such as ECMO, Gait Laboratories, cardiac catheterisation, interventional neuroradiology.

Quality and safety

- Is concentration of services required to maintain expertise and ensure satisfactory outcomes?
- Scope of credentialing and competency assurance is needed to ensure safe implementation of the technology.

Facilities

- Specialised equipment that would / should only be available at a few centres.
- Specialised requirements for the use or housing of the equipment.
- Specialised facility requirements.

Cost

- Are there high costs, training, staffing costs or economies of scale associated with use of the technology with the result that concentrated services are more cost efficient?
- High capital costs such as equipment costs over, for example, \$500,000, or, specialised construction requirements.

ASSESSMENT OF A PROPOSAL TO ESTABLISH A NFC NATIONALLY FUNDED CENTRES (NFC) PROGRAM

This pro forma is to be used by the assessing body engaged by the NFC Reference Group to undertake and report on a full health technology assessment (HTA) of a proposed NFC.

The assessing body will undertake the HTA with the support of personnel with expertise, as required, in the clinical specialty, health services planning, health economics and technology assessment, and including representation from the NFC Reference Group.

The experts should be drawn from relevant clinical disciplines in varying States and Territories. It is critical that any conflicts of interest are disclosed before parties are involved in this process.

Given the specialised nature of technologies proposed for NFC status, input is also required from international experts to assist in independent assessment. Experts with recent and relevant offshore experience (within the last 5 years) would be suitable in most cases, however for more contentious assessments, an expert who is living and working overseas should be engaged.

The overarching principle in considering a technology / clinical practice (technology) for provision as a NFC is whether this will maintain or improve quality of care and equity of access for Australian patients.

For each specific HTA, the NFC Reference Group will negotiate and agree structures and processes to undertake the work including roles, responsibilities, reporting, timelines and consultation with jurisdictions, with the assessing body prior to commencement of the assessment. The negotiations should ensure that the scope of the work is clearly understood by the assessing body. The assessing body will also need to give consideration to and manage any conflicts of interest.

The elements to be addressed in the report of the assessment of the submission for a technology / clinical practice to be provided as a NFC are detailed below.

Nature of the technology and clinical need

Description and classification of new technology

- Describe the technology and its application.
- Specify whether this is either a new technology; or a substitute or replacement for an existing technology.

Clinical indication / disease / condition (s) for treatment by proposed technology/clinical practice

- Specify the condition(s) which will be treated by the technology.
- Provide information on the incidence and prevalence of these conditions in Australia.

Patient population(s) and projected demand for proposed technology

- Describe the demographic characteristics of the patient population(s) with the clinical condition.

- Detail the factors to be taken into account when considering patient selection and clear criteria for patient selection onto the program.
- Provide information on the predicted number of patients per annum who may benefit from the technology and potential changes in the number of patients who may benefit within the next 5 to 10 years.

Health outcomes for new technology

- What health outcomes will be achieved?
- How could the health outcomes be measured?
- Over what time frame will these outcomes occur?

Use of new technology

- Describe use of the technology nationally and internationally.

Comparison with existing approach(es) to clinical intervention

- What existing technology(s) is / are used for the clinical condition?
- Describe key differences in the indications, contra-indications, cautions, warnings and adverse effects between the proposed technologies.

Ethical issues

- Are there ethical issues to be considered in establishment of the technology?

Safety and clinical effectiveness

Regulatory approval of the new technology

- Provide evidence of approval and approval date for the technology for use in Australia for the specified clinical problem(s) for service provision (as opposed to approval for a trial) by the Therapeutic Goods Administration or other regulatory agencies as indicated.

Evidence of safety of the new technology

- Provide evidence regarding safety associated with the use of the technology for the proposed clinical indication.
- Provide evidence on the nature and incidence of side effects, contra-indications, cautions, warnings and adverse effects for technology and the proposed indication, and source of this information.

Evidence of clinical effectiveness of the new technology

- Detail evidence of clinical effectiveness of the technology for the defined clinical problem(s).
- Identify and summarise scope, methodology and outcomes of health technology assessment undertaken for the technology by other agencies.
- Identify and summarise clinical guidelines and / or guidance on use of the technology / practice from agencies and professional bodies.
- Identify and summarise evidence and / or practice relating to quality outcomes and throughput for an organisation and / or clinical team and / or individual provider.
- Identify and describe any particular issues from the evidence about this technology / clinical practice that may influence its implementation in the public sector.
- Identify and describe aspects of the technology that require further evaluation.

Service delivery

Model of care and service delivery

- Comment on the information provided in the NFC submission on the model of care and service delivery, taking into account evidence on safety and effectiveness and considering the following elements:
 - service scope;
 - continuum of care;
 - workforce;
 - clinical infrastructure;
 - specialised equipment requirements;
 - facilities (bed and NFC specific establishment requirements);
 - relationship with, and provision of information to, referring practitioners;
 - outreach services in other jurisdictions;
 - teaching and training requirements; and
 - current and proposed research.

Financial implications

Cost effectiveness

- Summarise evidence on cost effectiveness for the technology from articles or other documents and / or from locations already providing the service.
- From this assessment, identify any costs which may be specific to Australia.

Cost estimates

- Comment on the cost estimates in the submission taking into account cost information in the literature and any costs which may be specific to Australia.

Synthesis of evidence and information supporting service concentration

National demand

- Provide evidence on the desirable patient throughput for an operator or team.
- Comment on whether the technology rapidly evolving to the extent that a limited number of teams are needed to keep up with developments.
- What requirement for further evaluation to determine its place in clinical practice before wider use in Australia would be appropriate?
- Experience and success in other jurisdictions.

Workforce

- Does the service involve complex multidisciplinary teamwork for which only a few centres could provide the full range of skills required, and the number of centres able to provide such teams could not readily be increased by training programs?
- Is the expertise to provide the service scarce and cannot be readily diffused by training programs?

Clinical infrastructure

- Associated clinical infrastructure such as intensive care, operating theatre, imaging, pathology, outpatients and such.
- Specialised clinical infrastructure such as ECMO, Gait Laboratories, cardiac catheterisation, interventional neuroradiology.

Quality and safety

- Is service concentration required to maintain expertise and ensure satisfactory outcomes?
- What is the scope of credentialing and competency assurance needed to ensure safe implementation of the technology?

Facilities

- Specialised equipment that would/should only be available at a few centres.
- Specialised requirements for the use or housing of the equipment.
- Specialised facility requirements.

Cost

- High capital costs such as equipment costs over, for example, \$500,000, or, specialised construction requirements.
- Are there high costs, training, staffing costs or economies of scale associated with use of the technology (such as one site operating / capital costs versus multiple sites operating/capital costs)?

Implementation and Establishment

Site determination

- Are there particular issues to consider in determining a site for establishment of the NFC taking into account assessment of all the evidence and information?

Number of sites

- On the basis of national and / or international experience, how many centres are optimal for Australia at this time?
- How many centres may be optimal in five and ten years?

Service delivery

- Are there policies, procedures and / or protocols (local or national) that would be clinically appropriate to develop and implement with establishment of the NFC?

Monitoring and evaluation

- Are there particular requirements for data collection, such as patient profile and outcomes, for ongoing monitoring of NFC activity?
- What technology specific data on adverse events should be collected for ongoing monitoring?
- Are there particular aspects of the NFC that should be monitored and considered in the NFC review?
- Should the NFC review be undertaken earlier than the standard three years and if so, why?

NFC SITE SELECTION – EXPRESSIONS OF INTEREST AND ASSESSMENT NATIONALLY FUNDED CENTRES (NFC) PROGRAM

This pro forma is to be used by jurisdiction(s) for an Expression of Interest to nominate a site for a new NFC and is to be provided to the NFC Reference Group via the NFC Secretariat.

Name of Technology / Practice

- Please specify.

Overview

Once the technology has been approved for NFC status by AHMAC, Expressions of Interest (EOI) for a site will be called from one or more jurisdictions.

A copy of the assessment of the technology will be available to jurisdictions to use as background for the EOI.

Where jurisdictions have already provided a submission to become a NFC, the NFC Reference Group will determine whether an EOI process needs to occur.

Areas to be addressed in the EOI for site nomination are:

Experience and expertise in providing the technology:

- Numbers of patients treated and over what timeframe.
- Health outcomes.

Institutional access:

- Is your institution prepared to accept patients for this technology from anywhere in Australia, or if more than one NFC is to be established, from a specified region of Australia, without giving preference to local patients?

Availability of all requirements and support services to provide a complete service:

- access to a broad range of clinical networks/specialities including retrieval networks.

Patient Care:

- Describe the approach to service delivery, patient selection and care, and interaction with referrers.

Quality and safety:

- Give details of the Quality and Safety Program that will be put in place if this proposal is accepted including quality of life and satisfaction considerations.

Data collection and evaluation:

- Specify the data that your agency will collect for monitoring and evaluation of the service and health outcomes, including technology specific adverse events.

Risk management:

- Identify the potential risks to the viability and operations of the service, such as workforce issues and reliance on external providers.
- Are there any constraints relating to transportation of organs, access for people from remote areas, other constraints that could occur due to the geographic location of your institution?
- What strategies would be established to mitigate these constraints and risks?

Implementation and Establishment:

- Describe how the site would approach the particular issues identified in the assessment report as specified by the NFC Reference Group.

Complete pro forma at Appendix 2 of the NFC Guidance document

- Completion of this pro forma is required for all EOIs.

Complete pro forma at Appendix 8 of the NFC Guidance document

- Completion of this pro forma is required for all EOIs.

REVIEW OF EXISTING NFCS NATIONALLY FUNDED CENTRES (NFC) PROGRAM

This pro forma is to be used by:

- *the reviewing body contracted by the NFC Reference Group to undertake a review of existing NFC; and*
- *existing NFC site(s) to prepare a report for the review.*

1. Introduction

NFCs are to be reviewed three years after they are established as a NFC and then every three years thereafter. However, the NFC Reference Group may request a review of an existing NFC be undertaken prior to the three years or at an extended period of up to a maximum of five years (refer to 6.1 for more information on the timing of reviews).

The NFC Reference Group will engage an agency to undertake the review. The NFC Reference Group will nominate three of its members to establish a Project Management Group to scope and oversee the review.

Reviews will be conducted in consultation with the host jurisdiction(s).

Host jurisdictions will be required to complete the costing pro forma at Appendix 2 in association with their report for the review.

The reviewing body may recommend undertaking a rapid review where there are changes in practice or evidence that do not require comprehensive evaluation.

The NFC Reference Group will negotiate and agree structures and processes to undertake the work including roles, responsibilities, reporting, timelines and consultation with jurisdictions, prior to commencement of the review. The negotiations should ensure that the scope of the work is clearly understood by the reviewing body. The reviewing body will also need to give consideration to and manage any conflicts of interest.

2. Review criteria

The elements to be reviewed for existing NFCs are detailed below. The status of each of these and any associated issues should be investigated.

Access to the NFC:

- numbers and referral sources of patients;
- clear criteria for patient selection (and, where they do not exist, a recommendation that such criteria be developed); and
- patient demographic information.

Health outcomes:

- mortality and morbidity;
- quality of life (specify instrument used for assessment of this);
- development: physical, cognitive etc (if applicable please specify); and
- other (if applicable please specify).

Model of care and service delivery:

- service scope;
- continuum of care;
- workforce;
- clinical infrastructure;
- equipment and facilities;
- relationship with, and provision of information to, referring practitioners;
- outreach services in other jurisdictions; and
- current and future service gaps and constraints.

Non-inpatient services:

- local outpatient services;
- outpatient services in other jurisdictions;
- service gaps and constraints; and
- continuum of care.

Quality and safety:

- adherence to treatment protocols and care pathways;
- adherence to agreed evaluation and reporting;
- inpatient complications;
- nosocomial infection;
- unexpected re-admission or return to intensive care;
- adverse incidents;
- NFC specific adverse events; and
- patient / family / carer satisfaction.

Teaching, training and research:

- ongoing teaching and training requirements and activities; and
- research achievements.

Clinical practice:

- recent or foreseeable changes in clinical practice in the NFC, including, but not limited to, changes in the clinical indications, patient population, and technology;
- evidence of substantive changes in existing NFC clinical practice; and
- development (with evidence) of existing comparative treatments / practices that could have an impact on the NFC and / or emerging new technologies that may substitute for existing NFC clinical practice.

Service demand:

- existing demand; and
- future demand taking into account changes in clinical practice.

Cost:

- cost(s) of the NFC and comparison of costs where there is more than one site;
- cost implications of changed clinical practice;

- consideration of costing studies (national and international) and any costs which may be specific to Australia; and
- the probable effect of increasing the number of NFCs on future NFC costs.

Risk management:

- other potential risks to the viability and operations of the service, such as workforce issues, availability of clinical infrastructure at the NFC host site, and reliance on external providers;
- constraints such as transportation of organs and access for people from remote areas, or other constraints due to the geographic location of the NFC; and
- strategies to mitigate these constraints and risks.

3. Need for continued service concentration

With reference to the above information, highlight factors supporting the need for continued service concentration, including but not limited to:

- the stage of development of the technology;
- health outcomes achieved to date;
- demonstrated and new evidence on the clinical and cost effectiveness of the existing clinical practice / technology and development of comparator treatments;
- previous and current estimates of the national and international demand for the technology / clinical practice Information on whether the technology / practice taking into account international practice;
- equity of access to the technology / practice; and
- cost.

Issues such as optimal throughput and critical mass to determine the number of sites and the point at which additional or fewer sites might be required should also be addressed.

4. Scope of recommendations

The possible recommendations from a review would be to:

- continue the existing activities of the NFC for a further defined period, with a further review to be conducted at the end of that period; or
- withdraw NFC status effective by 30 June in the next calendar year from the date of the decision.

If a decision is made to continue the existing activities of the NFC, the following outcomes may also be recommended:

- address and rectify issues identified by the review team;
- modify the scope of services and care provided by the NFC to meet current clinical and service requirements;
- reduce, maintain or increase the level of activity; or
- reduce, maintain or decrease the number of NFC sites providing the service.

A review may be undertaken in less than three years where there has been:

- a recommendation for this with a new NFC;
- an unforeseen issue with an existing NFC;
- unforeseen changes in clinical practice whereby the NFC is no longer required; or
- emergence of an unforeseen substantive change in clinical practice that changes the scope of services provided by the NFC and has significant financial implications.