

**NATIONALLY FUNDED CENTRES  
GUIDANCE  
FOR  
GOVERNANCE, MANAGEMENT, FUNDING, ESTABLISHMENT, REVIEW**

**AUSTRALIAN HEALTH MINISTERS' ADVISORY COUNCIL**

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## **1.0: 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 (technology) with limited demand. This is the Nationally Funded Centres (NFC) Program.

## **2.0: Purpose of the Guidance**

The purpose of this Guidance is to ensure that there is transparency and openness in the NFC processes and the information collected and to provide information on the following:

- Governance, Management, Administration and Funding of the NFC Program;
- Nomination of a proposed NFC;
- Assessment of proposed NFCs;
- Establishment of new NFCs;
- Review of NFCs; and
- Cessation of NFC.

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

## **3.0: 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;
- health and cost outcomes of these technologies are monitored and evaluated; and

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 also 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 these 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 shorter, 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 will be charged the full cost of the service, subject to any reciprocal arrangements agreed with the overseas country.

#### **4.0: Governance, Management, Administration and Funding**

##### **4.1: Governance**

The Australian Health Minister's Advisory Council (AHMAC), has been appointed by the AHMC to oversee all aspects of the NFC Program and associated policy.

##### **4.2: Management and Administration**

The NFC Reference Group reports to AHMAC through the Health Policy Priorities Principal Committee (HPPPC) and is responsible for the planning and management of the NFC Program; for ensuring submissions for new NFCs are assessed (subsequent to approval by AHMAC); and, the review of existing NFCs every three years, and at other times as indicated. The Reference Group also determines the annual budgets for NFCs.

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 MSAC and HealthPACT can attend NFC Reference Group meetings as observers.

Administration of the Program is undertaken by a host jurisdiction nominated by AHMAC.

An assessing body will be engaged by the NFC Reference Group on behalf of AHMAC to undertake technology assessments for proposed technologies/ clinical practices as required. The assessing body will provide recommendations to the NFC Secretariat on the establishment of new NFCs. The NFC Reference Group will then review these recommendations in conjunction with a range of policy and service planning issues in order to make recommendations to AHMAC. Reviewing bodies will also be engaged to review existing NFCs and make recommendations on the continuation or cessation of existing NFCs. The NFC Secretariat will prepare a report to AHMAC, through the HPPPC, based on consideration of the assessing/reviewing body's recommendations.

The NFC Reference Group will ensure appropriate project management of the required assessments and reviews in consultation with the assessing/review body.

This will include consideration of:

- structures and processes to undertake the work;
- roles and responsibilities;
- scope and content of 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 NFCs, refer Appendix One.

#### **4.3: Funding**

Funding is provided for the NFC Program by the State and Territory jurisdictions. This includes funding for individual NFCs, the cost of the Secretariat and the cost of any relevant assessments and reviews.

The contribution from each jurisdiction is based on a population-based formula.

The funding will be indexed annually by the Consumer Price Index plus 0.5%.

AHMC originally agreed that Nationally Funded Centres would be funded from a pool established by contributions from the Australian Department of Health and Ageing and across all States and Territories. However, since 1998, the Department of Health and Ageing, has broad-banded its contributions through the Australian Health Care Agreement.

The funds are pooled into a separate fund which is operated by the AHMAC Secretariat.

States and Territories make payments to the AHMAC Secretariat which in turn pays those jurisdictions that are net recipients.

#### **4.4: Cost of Procedures and Services**

The cost of procedures will include costs for services spread across the predicted numbers of patients per annum. Initially costs will be determined, on the basis of the care pathways and costings provided in the submission for a new NFC, and taking account of the advice provided by the assessment body. For costing proforma refer to Appendix Two.

A clear definition of the start and end point for the episode of care of the individual NFC Program is required. This 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. If the projected costs are based upon historical data, this needs to be clearly identified.

At the time of assessment of the appropriateness of the 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 needing to be undertaken by the NFC team.

This will be taken into account when the NFC Reference Group assesses service arrangements and funding.

Cost data is required from jurisdictions at four points:

1. when nominating jurisdictions provide comprehensive submissions (refer section 5.2);
2. when jurisdictions provide information to support their expression of interest to host a site (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 NFC price after establishment and before the next scheduled review (as described in this section)

The NFC Reference Group will recommend through HPPPC to AHMAC the commissioning of a review of all NFC procedures three years after initial establishment. Future reviews will be every three years.

As part of these reviews, service delivery issues, costs and funding will be reviewed by the NFC Reference Group.

The NFC Reference Group may request a review be undertaken prior to the three year review process due to:

- a change in clinical practice that has resulted in significant cost increases to provide procedures;
- a technology changes more quickly; or
- where there is a plan to undertake an earlier review as part of the initial endorsement of a NFC or a recommendation of the previous review.

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

A NFC, can also 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 which have increased the cost of providing that procedure.

A price review will be considered by the NFC Reference Group in the first instance with expert advice to be sought as required.

The outcome of a price review will be implemented by an adjustment to the next NFC annual budget to reflect revised prices where approved by the NFC Reference Group.

#### **4.5: Process for 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 the previous year and future year activity estimates. Centres providing the same services and procedure type (e.g. same transplant procedure) will receive the same amount of funding in accordance with the agreed rate per procedure plus indexation.

The NFCs will be required to operate within their fixed budgets with no adjustments for variations in procedures within the current financial year. Any cost overruns are to be met by the state in which the NFC is located.

All jurisdictions will also be required to make a contribution towards the following:

- cost of the NFC Secretariat. The total contribution by all States and Territories for the Secretariat is \$50,000 per annum from 2004/05, indexed annually by CPI plus 0.5%.
- costs of assessments and reviews if required, 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 contribution from each State is based on the percentage of the weighted population of Australia.

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

1. In line with NFC annual reporting requirements, by mid July each year, each NFC via its jurisdiction, will submit 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. Refer Appendix Three.
2. Subject to the receipt of data, the NFC Secretariat will provide a consolidated draft budget to all Reference Group members by the end of July. The draft budget will include:
  - the estimated number and type of procedures by State or Territory for the current year adjusted for the difference between the estimated and actual number of procedures performed in the previous year;
  - the cost per procedure;
  - payments to States and Territories with NFC sites for the current year;
  - payments for assessments and reviews if required;
  - payments for the NFC Secretariat; and
  - the total contribution of each State or Territory is derived from the weighted population formula.
3. Responses to the draft budget should be provided to the NFC Reference Group Secretariat promptly following receipt of the draft budget and by mid August at the latest. This 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. The NFC Reference Group meets at the end of August and agrees to the final budget details. The NFC Reference Group will provide an out of session briefing to AHMAC through HPPPC on the budget for noting.

5. In early September the NFC Secretariat requests the AHMAC Secretariat to send two invoices to all States and Territories requesting their contribution for:
  - The NFC approved sites and the cost of assessments and reviews if required; and
  - The NFC Secretariat.Jurisdictions hosting NFCs will be asked to pay the difference between what they should contribute and what they should receive as a NFC provider.
6. Jurisdictions will make their contributions by the end of September.
7. The NFC Secretariat, through the AHMAC Secretariat, will make one annual payment to net recipients in October of each year.

#### **4.6 NFC Reporting Requirements**

NFCs will be required to provide annual reports by mid July each year on the following:

- Patient numbers and demographics
- Patient outcomes specific to, and as agreed for, individual NFCs
- Quality and safety indicators including
  - nosocomial infection;
  - adverse clinical events;
  - unplanned readmission to intensive care;
  - unplanned readmission post discharge;
  - quality of life;
  - patient/family/carer satisfaction; and
  - others specific to and agreed with individual NFCs
- Significant modifications to the treatment being provided by the NFC along with the cost implications and evidence to support these modifications;
- An update of the status of use of the technology and associated patient outcomes in international jurisdictions; and
- Anticipated demand for the coming year.

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. Factors to also be considered in determining appropriate allocations will include improving patient access and maintaining sufficient throughput at existing units to ensure maintenance of skills and efficiency in service provision.

A proforma for the above information is at Appendix Three.

## **5.0: Establishment of new Nationally Funded Centres**

For summary of the nomination, and assessment, and site selection process, refer to the flow chart in Appendix Four. The key steps are as follows:

- Nomination of a proposed technology;
- Approval by AHMAC to progress with assessment of the technology for NFC status;
- Assessment of the technology; and
- Recommendation to AHMAC through HPPPC by the NFC Reference Group regarding eligibility and factors to be considered in determining the number and location of centres

If NFC status for the technology is approved by AHMAC, Expressions of Interest for a site (s) will be called from jurisdictions.

### **5.1: Nomination of a technology proposed as a NFC**

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

The focus of this stage is to have an assessment of the **technology** undertaken. Site nomination does **not** occur.

Joint jurisdictional nominations are encouraged but not mandatory.

The following information is required to be detailed **in no more than five pages**:

- Description and Classification of New Technology
- Clinical indication/disease/condition for treatment by proposed new technology/clinical practice
- International and National practice
- Evidence of clinical and cost effectiveness
- Benefits of the technology
- Estimation of the likely level of national demand and
- Requirement to be planned and delivered on a nationally consistent basis.

A proforma outlining these requirements is provided at Appendix Five

Nominations for new NFCs received by the NFC Secretariat after COB 30 June and before COB on the second Monday of December will be considered at the NFC Reference Group meeting in February the following year. Nominations for NFCs received after COB of the second Monday of December and prior to COB 30 June will be considered at the NFC Reference Group meeting in August of that year.

The NFC Reference Group will:

- review documentation;
- comment on the nomination;
- make a recommendation to AHMAC, through HPPPC, to progress the assessment of the technology for consideration as a new NFC as agreed, or non-support, as required;
- provide information to contribute to assessment of the technology; 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 through HPPPC to AHMAC, and reasons for this decision will be made available.

If the NFC Reference Group believes that the technology is not appropriate for assessment, and the nominating jurisdiction(s) wish(es) the nomination to be forwarded to AHMAC, it will be submitted with the majority recommendation, noting the dissent.

The NFC Secretariat will prepare and forward a proposal through HPPPC to the next AHMAC meeting 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 *Submission(s) for consideration of a technology by nominating jurisdiction(s)***

If there is AHMAC approval to proceed, the nominating jurisdiction(s) will be required to prepare a full and comprehensive submission to the NFC Secretariat.

Joint jurisdictional submissions are encouraged but not mandatory.

The proforma for the full submission and information required is provided in Appendix Six. Costing details need to be provided in accordance with the costing template at Appendix Two. In providing this information, jurisdictions should be mindful of the potential for patients to be identifiable where numbers are small and the need for patient privacy may be more acute. Jurisdictions are also responsible for ensuring that the data provided to support NFC submissions is accurate.

The jurisdiction(s) should complete the submission within three months of receiving formal advice from the NFC Secretariat of AHMAC approval.

## **5.3 *Assessment of a proposed NFC***

The NFC Reference Group will contract an assessing body to consider and advise on the suitability of the technology for inclusion in the NFC Program. The 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 and agree structures and processes to undertake the work including roles, responsibilities, reporting, scope of work, timelines and communication with the assessing body prior to commencement of the assessment. This will include consideration of conflicts of interest.

The NFC Secretariat will forward the submission(s) to the assessing body for a Health Technology Assessment (HTA) and to all jurisdictions for information.

The assessing body undertaking the HTA will comprise evaluators with significant experience for this work. It will include personnel with expertise in the clinical specialty, health services planning, health economics and technology assessment. Given the specialised nature of technologies proposed for NFC status, input may also be required from international experts.

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

Key considerations of the assessing body are:

- Inclusion of the technology in the NFC program will maintain or improve quality of care and equity of access for Australian patients; and
- the need to concentrate the service, balanced with a level of demand that can be met by one to two centres nationally to optimise access.

The assessing body will also consider particular issues that may be appropriate for implementation and establishment of NFCs including, but not limited to, criteria for site selection, monitoring and evaluation, 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 are to only reflect the agreed scope of the review. Comments regarding issues outside the stated scope of the review 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 final draft 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 to the assessing body to enable the assessing body to finalise the report.
- The assessing body will consider the comments provided, and provide jurisdictions making comment on the report with a formal response to those comments
- The assessing body finalises the report and formally refers it to the NFC Reference Group.

#### **5.4 Approval of NFC Status**

Following the HTA, recommendations will be made to the NFC Reference Group on the suitability or unsuitability of the technology for a NFC. The recommendations will also include whether there should be more than one NFC and the criteria for selecting a site to be the NFC.

Based on these recommendations of the assessing body and considerations of other factors as appropriate, the NFC Reference Group will provide a recommendation (including any dissenting view) to AHMAC through HPPPC regarding the suitability or unsuitability of the technology for NFC status; and if NFC status is approved, seek agreement to proceed with site selection.

## **5.5 Site Selection –Nomination Expression(s) of Interest and Assessment**

### **Expression(s) of Interest**

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. 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 be used 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, patient selection and care, 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
- Implementation and establishment strategies

Completion of the templates at Appendices Two and Eight is required for all EOIs and these provide additional detail on the information required..

### **Site Assessment**

The NFC Reference Group will recommend to AHMAC through HPPPC one or more NFC sites 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. This includes access for persons requiring treatment including 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 & development;
- Any auxiliary associated services required (e.g. 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.

If there are queries about a proposed site or there are a greater number of sites than recommended by the assessing body, and if the NFC Reference Group not reach agreement on the site(s), the assessing body may be requested to provide some further advice in regard to site selection.

The NFC Reference Group will then make a recommendation through HPPPC to AHMAC on the site(s).

## **5.6 Establishment of the NFC**

Once the site(s) has been approved by AHMAC the NFC Secretariat, on behalf of AHMAC is to formally notify:

- the relevant State or Territory health authority(ies);
- all other jurisdictions;
- the Chair of the NFC Reference Group;
- assessing bodies; and
- other relevant bodies.

The NFC Reference Group will confirm finalised funding requirements from the host jurisdiction(s). The NFC Secretariat will then:

- calculate the financial implications for all jurisdictions; and,
- submit a financial proposal through HPPPC to AHMAC for endorsement.

The proposal to AHMAC will include any special conditions for the NFC and the appropriate agreed date for review. It will also include arrangements for data to be collected for annual reporting such as evaluation of health, safety and quality, scientific, equity access and resource utilisation outcomes. Jurisdictions are also responsible for ensuring that the data provided as part of the annual review of NFC programs 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 while a technology is funded under the NFC program, the technology will not be set up at an additional site used outside of the program. Through funding and regulatory arrangements, States, Territories and the Australian Government should encourage through their funding and regulatory arrangements strong disincentives to the proliferation of both public and private sector services for the NFC technology.

## **6.0 Regular Reviews of Nationally Funded Centres**

The NFC Reference Group will recommend to AHMAC the commissioning of a review of all NFCs three years after initial establishment. Future reviews will also be every three years.

The NFC Reference Group may request a review be undertaken prior to the three year review process due to:

- a change in clinical practice that has resulted in significant cost increases to provide procedures;
- a technology changes more quickly; or
- where there is a plan to undertake an earlier review as part of the initial endorsement of a NFC or a recommendation of the previous review.

Subsequent to AHMAC agreement for a review, the NFC Reference Group will contract a body to undertake this review. The Reference Group will not necessarily undertake a full procurement process for required work but will make a decision on the reviewing body taking into account expertise/ ability, track record, quality of the work, value for money and timeframes.

The NFC Reference Group will negotiate and agree structures and processes to undertake the work including roles, responsibilities, reporting, scope of work, timelines and communication with the reviewing body prior to commencement of the review. This will include consideration of conflicts of interest.

Subsequent to this, 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 potential for patients to be identifiable where there are small numbers and the need for patient privacy. Jurisdictions are also responsible for ensuring that the data provided for the review process is accurate.

Criteria to be considered as part of the review are listed in Appendix Nine and include:

- Access to the NFC
- Health outcomes
- Model of care and service delivery
- Quality and safety
- Teaching, training and research
- Changes to clinical practice
- Service demand
- Cost.
- 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 technology / practice
- Cost
- Issues such as optimal throughput and critical mass to determine the number of sites and the point at which additional site(s) might be required.

The possible recommendations from a review will be to:

- Continue the existing activities of the NFC at a reduced, equal 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 NFCs providing the service;
- Increase the number of NFCs providing the service;
- Cease NFC status effective by 30 June in the next calendar year from the date of the decision.

As part of the continuation of the activities of the NFC the following recommendation may also be made:

- 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.

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

- Satisfactory health and cost-effectiveness outcomes have been achieved;
- Existing centre(s) does 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 centre or centres is similar to that of the first centre;
- Establishment of an additional centre or centres will not adversely affect health outcomes; and,
- Establishment of an additional centre or centres will not adversely affect equity of access.

A balance will need 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 NFCs is appropriate, then agreement will be reached on the timing of a further review.

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.

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

- A final draft 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 to the assessing body to enable the assessing body to finalise the report.
- The assessing body will consider the comments provided, and provide jurisdictions making comment on the report with a formal response to those comments
- The assessing body finalises the report and formally refers it to the NFC Reference Group.

## **7.0: Cessation of a Nationally Funded Centre**

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 this is at a point when not all States or Territories are providing the service, the usual arrangements for State 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.

When AHMAC approves the withdrawal of NFC status, those centre(s) affected will cease as a Nationally Funded Centre effective by 30 June in the next calendar year.

## ROLES AND RESPONSIBILITIES

### *The Australian Health Ministers Advisory Council*

The Australian Health Ministers Advisory Council (AHMAC) has been appointed by the AHMC to oversee all aspects of the NFC Program and associated policy. This includes considering all recommendations forwarded to it by the NFC Reference Group and making decisions. AHMAC also adjudicates on matters where the Reference Group is unable to make a recommendation. The NFC Reference Group reports to AHMAC through the Health Policy Priorities Principal Committee (HPPPC).

### *The Assessing Body*

The assessing body is 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.

### *The Reviewing Body*

The reviewing body is 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.

### *NFC Reference Group*

The NFC Reference Group is established by AHMAC. It will comprise a representative from the Australian Government and each State and Territory. The Reference Group will be responsible for making recommendations to AHMAC regarding proposals for new technologies and recommendations regarding the outcome of the review. It will be responsible for determining the annual operating budgets for approved NFCs and for the general administration of the program. It will also develop and maintain interfaces with relevant bodies including HealthPACT and MSAC in order to maximise effective consideration of health technology issues and avoid duplication of effort. The NFC Reference Group will meet as required.

### *NFC Reference Group Secretariat*

The NFC Reference Group Secretariat is responsible for ensuring that the Guidance for the NFC Program is routinely examined and updated in consultation with States and Territories and NFC units. It is also responsible for administering the NFC budget process, including the collection and analysis of data, including that necessary for budget setting purposes

### *State and Territory Health Departments*

The role of the States and Territories is to:

- participate in NFC processes, including through the technology assessment process and reviews, and the NFC Reference Group as appropriate;
- host designated NFC services in accordance with agreed Guidance;
- 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.

### *Australian Government*

The role of the Australian Government is to participate in NFC processes, including through the technology assessment process, and the NFC Reference Group as appropriate

**COSTING PROFORMA  
NATIONALLY FUNDED CENTRES PROGRAM**

The following costing data is to be completed when:

- nominating jurisdictions provide comprehensive submissions (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 the 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 NFC price, after establishment and before the next scheduled review (refer section 4.4).

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: .....

## **OVERVIEW**

This proforma is a guide to the level of information and data required for the review process and any queries about what should be included should be discussed with the jurisdictional representative on the NFC Reference Group from your State or Territory government Department. The submission must be directed through this Department for review and sign-off. The proforma outlines the methodology and types of costs to be completed for all costing submissions.

Detailed information is to be provided on:

- Establishment costs, which may include 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
- Direct and indirect operational costs for the patient care pathway;
- Facility and equipment costs; and,
- Projected annual costs.

### **1. CARE PATHWAY COSTS**

This incorporates direct patient costs for each phase of patient care including indirect patient costs and health service / hospital overheads. The costing information should reflect the median cost per patient.

Where there is more than one patient care pathway in the NFC with substantially different care elements and cost implications, separate care pathway costs should be developed.

The costs of those patients who receive an assessment and work-up but do not proceed to the procedure stage also need to be considered.

#### **1.1: 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. Only costs incurred at the NFC site are to be included. The suggested phases of care are:

- Referral to Service
- Preliminary diagnostic testing and work-up
- 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 Program
- 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;
- The 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.

## **1.2: In-Direct Patient Costs**

These are:

- NFC Program Management: 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 overheads: These costs are generally calculated as a percentage of the direct patient care costs.

## **1.3: Detailed Care Pathway Costs**

Table One is a template 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;
- MBS scheduled fees.

**TABLE ONE: Detailed Care Pathway Costs based on median costs**

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

<b><u>7. HIGH DEPENDENCY UNIT / INTENSIVE CARE ADMISSION</u></b>				
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)				
<b>SUB-TOTAL INTENSIVE CARE</b>				
<b><u>8. GENERAL WARD ADMISSION</u></b>				
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)				
<b>SUB-TOTAL WARD ADMISSION</b>				

<b><u>9. OUTPATIENT CARE PRIOR TO DISCHARGE FROM THE NFC PROGRAM</u></b>				
Consumables				
Medical Monitoring				
Specialist Nursing Monitoring				
Surgical Review				
Allied Health Monitoring / Review				
Nutrition				
Drugs / Pharmacy (excluding S100)				
Imaging				
Pathology				
Other (please specify)				
<b><u>10. OTHER DIRECT PATIENT COSTS</u></b>				
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)				
<b>SUB-TOTAL OTHER DIRECT COSTS</b>				
<b>TOTAL DIRECT COSTS</b>				

<b>11. OVERHEADS / INDIRECT COSTS</b>				
<b>PROGRAM MANAGEMENT</b>				
Unit Head				
Administrative / Clerical				
CNC Nurse Co-ordinator				
Other (please specify)				
<b>SUB-TOTAL PROGRAM MANAGEMENT</b>				
<b>ADMINISTRATION &amp; OVERHEADS</b>				
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				
<b>SUB-TOTAL OTHER COSTS AND OVERHEADS</b>				
<b>TOTAL IN-DIRECT COSTS</b>				
<b>GRAND TOTAL DIRECT &amp; INDIRECT COSTS</b>				

## **2.0: 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.

### **2.1: 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:

- 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 Two:

**TABLE TWO: NFC Equipment**

Item	Purchase Price	Justification	Repair cost	Maintenance	Depreciation

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

## 2.2: 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;
- 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 Three:.

**TABLE THREE: NFC Facility Enhancements**

Description	Cost	Justification

### **Use of Health Service / Hospital Facilities**

The following needs to be addressed:

- a) Detail expected bed utilisation by NFC patients, the analysis to support use of this number of beds, and numbers of staffed and funded beds in the following treatment ward locations as indicated in Table Four.

**TABLE FOUR: NFC Bed Utilisation**

Treatment Ward	NFC Beds	Total Beds	Total Est Area M <sup>2</sup>
ICU			
High Dependency			
General Ward			
<b>Total</b>			

- b) Detail the proposed NFC use of other facilities with the duration of NFC specific and usual use, estimated area and the analysis to support the use of these facilities, as per Table Five.

**TABLE FIVE: NFC Facility Utilisation**

Facility	NFC Hrs/Wk	Total Hrs/Wk	Total Est Area M <sup>2</sup>
Theatre			
Procedure Room (specify)			
Treatment Room			
Other (specify)			
<b>Total</b>			

- c) Estimated NFC share of facilities and proposed rental

Treatment Wards

- Total beds
- Space equivalent:

Other facilities:

- Space equivalent:

Notional rental

- Rent/ M<sup>2</sup> per annum
- Rent per annum

**3. SUMMARY OF TOTAL ANNUAL PATIENT COSTS**

**3.1: Total Cost: All Patient Pathways**

**TABLE SIX: Total Cost: All Patient Pathways**

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

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

### 3.2 Projected Annual Costs for the Life of the NFC: 3 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 median 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 SEVEN: Projected NFC Costs**

	Year One	Year Two	Year Three
Patient Nos all pathways			
<b>Cost / Patient all pathways</b>			

## APPENDIX THREE

### PROFORMA FOR ANNUAL STATISTICAL RETURNS NATIONALLY FUNDED CENTRES 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.

Financial Year Ending: \_\_\_\_\_

State / Territory: \_\_\_\_\_

Health Service / Hospital: \_\_\_\_\_

Name of NFC: \_\_\_\_\_

#### 1. Summary information of patient numbers

TABLE 1.1 New referrals

State or Territory of patient residence	New referrals	Accepted	Not accepted
NSW			
VIC			
QLD			
WA			
SA			
TAS			
ACT			
NT			
Overseas (advise country) Refer Section 3 of Guidance			
TOTAL			

TABLE 1.2 Current Patients\*

State or Territory of patient residence	Awaiting Treatment		Treated	
	A Accepted this year	B Accepted previous year(s)	C Accepted this year	D Accepted previous year(s)
NSW				
VIC				
QLD				
WA				
SA				
TAS				
ACT				
NT				
Overseas (advise country)				
<b>TOTAL</b>				

\* All patients to be identified for the reporting year irrespective of awaiting treatment, treated or treatment outcome. This should also include death while awaiting treatment and post treatment. The total number of patients in columns C plus D should equal the total number of patients in Table 1.4.

TABLE 1.3 Discharges from NFC\*

State or Territory	Number of patients exiting while awaiting treatment (including deaths)		Number of patients discharged post-treatment (irrespective of death)
	Patients exiting	Patients exiting due to death	
NSW			
VIC			
QLD			
WA			
SA			
TAS			
ACT			
NT			
Overseas (advise country)			
<b>TOTAL</b>			

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

1.4 Types of patient outcomes during the year \*

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	

\*or as amended for individual NFCs as agreed with the NFC Reference Group

**2. Outcome measures**

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

2.1 Nosocomial infection – Occurred during the year – yes/no

Details

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---

2.2 Adverse clinical events - Occurred during the year – yes/no

Details

---

---

2.3 Unplanned readmission to intensive care – - Occurred during the year – yes/no

Details

---

---

2.4 Unplanned readmission post discharge - Occurred during the year – yes/no

Details

---

---

2.5 Quality of Life (measurement used to collect information as agreed as per Section 4.6 of the Guidance)

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---

2.6 Patient/family/carer satisfaction (measurement used to collect information as agreed as per Section 4.6 of the Guidance)

---

---

2.7 Other outcome measures specific to, and as agreed with, individual NFCs.

---

---

2.8 Patient and transplant survival figures:

	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

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---

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 template (Appendix Two)

### 5. Anticipated demand

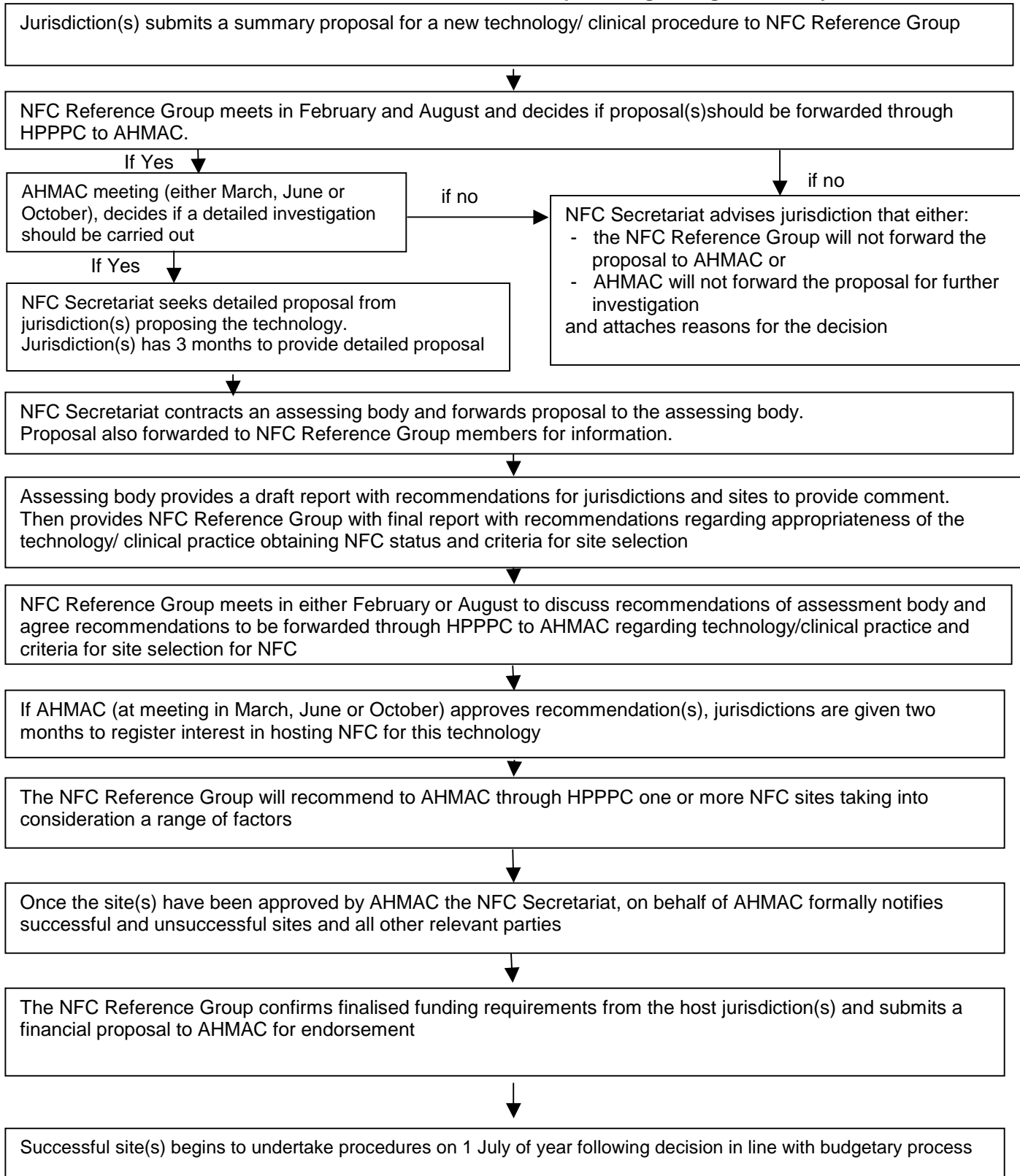
Estimated number of procedures to be performed in this coming year xx/xx:

---

## APPENDIX FOUR

### PROPOSAL/SUBMISSION/APPROVAL FLOW CHART FOR A NEW NFC

Nominations for new NFCs received by the NFC Secretariat after COB 30 June and before COB on the second Monday of December will be considered at the NFC Reference Group meeting in February the following year. Nominations for NFCs received after COB of the second Monday of December and prior to COB 30 June will be considered at the NFC Reference Group meeting in August of that year.



**NOMINATION SUMMARY TEMPLATE FOR NEW NATIONALLY FUNDED CENTRE**

This proforma is to be used by jurisdiction(s) seeking to nominate a new nationally funded centre and provided to the NFC Reference Group via the NFC Secretariat. For detail on the criteria required to be considered as an NFC refer to section 3.0 of the guidance

**Name of Technology/Procedure**

**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 new 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**

The extent to which the proposed technology is in practice, internationally, or in Australia. This should include an indication of the current utilisation of the technology, 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*

- Description of existing technologies/procedures that this would replace
- 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.**

## COMPREHENSIVE SUBMISSION TEMPLATE FOR NEW NATIONALLY FUNDED CENTRE

This proforma 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 new 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.

#### **Patient Population(s) and Projected Demand for proposed new 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
- 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**

- Provide information on 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 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) 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;
- 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
- Collaboration with international centres

## **Financial Implications**

### **Cost and Budget**

- To be completed in the template as at Appendix Two – Costing Proforma.

### **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 NATIONALLY FUNDED CENTRE

This proforma is to be used by the assessing body engaged by the NFC Reference Group to undertake and report on a full assessment 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. Input from international experts may also need to be sought.

The overarching principle in considering a technology / clinical practice (technology) for provision as a Nationally Funded Centre (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, roles, responsibilities, reporting, scope of work, timelines and communication with the assessing body prior to commencement of the assessment. This will include consideration of 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 new 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.

#### **Patient Population(s) and Projected Demand for proposed new 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
- 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**

- Confirm evidence of approval and approval date for the technology for use in Australia for the specified clinical problem(s) 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
  - 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.
- 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.
- Expertise to provide the service is 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

catherisation, interventional neuroradiology

### **Quality and Safety**

- Is service concentration 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**

- 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 - ie 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 3 years and if so, why ?

**NEW NATIONALLY FUNDED CENTRE  
SITE SELECTION – EXPRESSION(S) OF INTEREST AND ASSESSMENT**

This proforma is to be used by jurisdiction(s) for an EOI to nominate a site for a new nationally funded centre and is to be provided to the NFC Reference Group via the NFC Secretariat.

**Name of Technology/Practice**

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

Completion of the templates as at Appendices Two and Eight are required for all EOIs.

**Review of Existing Nationally Funded Centres**

This proforma 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**

Nationally Funded Centres (NFC) should be reviewed at least every three years. The NFC Reference Group will engage an agency to undertake this review, and in consultation with the reviewing body will establish a Steering Committee to scope and oversee the work. This Committee will include representation from the NFC Reference Group, experts in the relevant clinical discipline(s), health services planning, health economics and evidence review from varying jurisdictions.

The experts should be drawn from relevant clinical disciplines in varying states and territories.

Input from international experts will also be sought as required.

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

Host jurisdictions will be required to complete the Costing Template as at Appendix Two 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, roles, responsibilities, reporting, scope of work, timelines and communication with the reviewing body prior to commencement of the assessment. This will include consideration of conflicts of interest.

**2. Review Criteria**

**The elements to be reviewed for existing NFC 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
- Patient demographic information

**Health Outcomes**

- Mortality

- Morbidity
- Quality of Life (specify instrument used for assessment of this)
- Development: physical, cognitive etc (if applicable please specify).
- Other (if applicable please specify)

### **Model of Care and Service Delivery**

- Service Scope;
- Continuum of Care;
- Workforce;
- Clinical Infrastructure;
- Equipment;
- Facilities;
- Relationship with, and provision of information to, referring practitioners;
- Outreach services in other jurisdictions
- Current and future service gaps and constraints

### **Non-inpatient services**

- Local outpatient services
- Outpatient services in other jurisdictions
- Service gaps and constraints
- 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
- Patient / Family / Carer satisfaction

### **Teaching, Training and Research**

- Ongoing teaching and training requirements and activities
- 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.
- 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;
- 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.
- The probable effect of increasing the number of NFCs on future NFC costs;

### **Risk Management**

- The 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, relating to transportation of organs, access for people from remote areas, or other constraints due to the geographic location of the NFC?
- What strategies would be established 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
- Cost

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

### **4. Scope of Recommendations**

The possible recommendations from a review will be to:

- Continue the existing activities of the NFC at a reduced, equal or increased level for a further defined period with a further review to be conducted at the end of that period. As part of the continuation of the activities of the NFC the following recommendation may also be made:
- 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;
- Continue the activities of the NFC at a reduced, equal or increased level for a further defined period with modifications as recommended and endorsed;
- Decrease the number of NFCs providing the service;
- Increase the number of NFCs providing the service;
- Cease NFC status effective by **30 June** in the next calendar year from the date of the decision.

As part of the continuation of the activities of the NFC the following recommendation may also be made:

- Address and rectify issues identified by the review team; and/or,
- Modify the scope of services and care provided by the NFC to meet current clinical and service requirements.

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.