

*The National Institute for Clinical Excellence*

# **Framework Document**

# ***The National Institute for Clinical Excellence***

## ***Framework Document***

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# **1 Introduction**

- 1.1 The National Institute for Clinical Excellence was established to promote clinical excellence and the effective use of available resources in the health service in England and Wales.
- 1.2 The Institute will set clear national standards which will help to improve the quality and consistency of NHS services throughout the country. These standards will form an important part of improving the overall health of the population and will help to tackle inequalities in health and access to care.
- 1.3 This service framework document explains how the Institute will conduct its work programme and highlights the links between the Institute and the Department of Health and the National Assembly for Wales.

## **2. Status**

- 2.1** The National Institute for Clinical Excellence (“the Institute”) is a Special Health Authority set up under Section 11 of the NHS Act 1977.
- 2.2** The order providing for the establishment and constitution of the Institute (SI 1999/220 ) was laid before Parliament on 3 February 1999 and came into force on 26 February 1999. This was amended by an order (SI 1999/2219) which was laid before Parliament on 6 August 1999 and came into effect on 27 August 1999.
- 2.3** The regulations which make provision concerning the membership and procedure of the Institute (SI 1999/260) were made on 4 February 1999 and came into force on 26 February 1999.
- 2.4** The Institute is accountable to the Secretary of State for Health and the National Assembly for Wales for its resources, delivery of its work programme and for the guidance it produces for the NHS.
- 2.5** The Secretary of State and the National Assembly for Wales have issued directions to instruct the Institute to carry out its functions. These directions are appended at Annex A..

### **3. Functions**

- 3.1 The Institute will promote clinical excellence and the effective use of available resources in the NHS through the development and dissemination of guidelines for the management of certain diseases or conditions, guidance on the appropriate use of particular interventions, audit methodologies and the dissemination of these to support frontline staff and patients.
- 3.2 The Institute will advise on good clinical practice in the use of existing treatment options, appraise evidence on new health interventions, and advise the NHS on how they can be implemented and how best they fit alongside existing treatments. The Institute will promote the appropriate use of those interventions which offer good value to patients and to discourage the use of those which do not.
- 3.3 For a more detailed account of the development and dissemination of clinical guidelines and audit methodologies see Annex B. For further details of the appraisal of individual health interventions see Annex C.
- 3.4 The Institute will co-ordinate the dissemination of information and respond to specific enquiries. It will provide a single reference point for information on clinical standards and audit methodologies.
- 3.5 The Institute will make every effort to support and compliment the NHS Information Strategy which aims to provide universal desk top access to the Institute's guidance.
- 3.6 The Institute will provide information to support implementation and to help local clinical teams. It will seek to ensure that its guidance is incorporated into continuing professional education programmes.

## **4. Structure of the Institute**

### **4.1** The Institute will have a board consisting of:

a non-executive chair, seven other non-executive members and four executive members, namely a chief executive, a finance director, a clinical director and a director of communications. In addition, the sponsor branch of the Department of Health will have an observer at all board meetings.

### **4.2** The appointment of the executive members will be through open competition. These appointments will be made by the Institute and approved by the Secretary of State for Health and the National Assembly for Wales.

### **4.3** The non-executive members will be appointed by the Secretary of State for Health and the National Assembly for Wales. All appointments will be made in accordance with the principles set out by the NHS Executive in *“The appointment of chairmen and non-executive directors to NHS authorities and trusts”* which was compiled in response to the recommendations of the Nolan Committee.

### **4.4** The Institute will also have a Partners’ Council that will be formed of representatives of key stakeholder groups (patients and carers, the health professions including the professional Royal Colleges, academics, NHS service interests and the pharmaceutical and other health care industries).

### **4.5** The Partners’ Council will review the Institute's annual progress report and contribute to the development of the work programme.

### **4.6** The chair of the Institute will also be the chair of the Partners’ Council. The chair will be responsible for appointing the other members of the Partners’ Council subject to the approval of the Secretary of State for Health and the National Assembly for Wales.

### **4.7** The Institute will have an appraisals committee that will advise the board of the Institute on the use of significant new and existing drugs and other health interventions. The chair of the appraisal committee will be appointed by the Institute subject to the approval of the Secretary of State for Health and the National Assembly for Wales.

### **4.8** The board of the Institute is subject to the Public Bodies (Access to Meetings) Act. The committees and sub-committees of the Institute are exempt from these provisions. The exception is if the Institute resolves itself into a committee or the committee or sub-committee is made up of all the members of the Institute. In either of those cases the requirement to meet in public does apply (See sections 1(6) and 2 (1) of the Public Bodies (Access to Meetings) Act.)

### **4.9** Rules for setting up further committees are laid out in the regulations (SI 1999/260).

## 5. Accountability

- 5.1 The Institute is accountable, through its chair to the Secretary of State for Health, (who is accountable to Parliament) and the National Assembly for Wales.
- 5.2 The Secretary of State for Health and the National Assembly for Wales will approve the corporate plan and the annual business plan described below.
- 5.3 The **Secretary of State for Health** and the **National Assembly for Wales** are responsible for:
- appointing and removing the chair and non-executive members;
  - setting the Institute's programme of work, in consultation with the chair and Chief Executive of the Institute;
  - advising the Institute about the NHS context / framework within which it will work;
  - determining, with the approval of HM Treasury, the remuneration of the chair and the non-executive members;
  - approving any variation from Whitley terms and conditions for the officers of the Institute;
  - receiving the Institute's annual statement of accounts;
  - giving directions, with the approval of HM Treasury, about the Institute's accounts;
  - determining, with the approval of HM Treasury, the Institute's financial regime.
- 5.4 The **board of the Institute**, through its chair, is responsible to the Secretary of State for Health and the National Assembly for Wales for the operational effectiveness of the Institute.

It is responsible for :

- the work of the Institute as directed by the Secretary of State for Health and the National Assembly for Wales. (For more details see Annex A.)
- monitoring the Institute's programme of work
- appointing the executive members of the Institute and determining their remuneration and conditions of service.
- monitoring the performance of the executive members of the board.

5.5 The chair is responsible for training, developing and appraising the performance of the non-executive members of the board.

5.6 The **chief executive of the Institute** is responsible for the day-to day management of the Institute and, in particular,

- for managing the Institute to ensure economy, efficiency and effectiveness in the operation of the Institute and the propriety and regularity of its expenditure.
- for developing personnel policies covering recruitment, grievance, discipline, appraisals and pay. These policies will be in line with current personnel practices in the NHS. Any departure from standard NHS procedure must first be agreed with the Department of Health and the National Assembly for Wales.
- for making sure that the Institute carries out its work in line with the Directions to the Institute issued by the Secretary of State for Health and the National Assembly for Wales (a copy of which can be found at Annex A.)
- being the Accountable Officer for spending by the Institute under Class XII, Vote 1.

5.7 The **chief executive of the NHS Executive** as overall Accounting Officer for the Vote is responsible for :

- ensuring that the conditions attached to any Department of Health and National Assembly for Wales funding of the Institute conform with the terms of the Vote;
- monitoring compliance with these conditions;
- being satisfied that the financial and other management controls applied by the Department of Health and the Institute's own management arrangements are sufficient to ensure value for money and propriety of all expenditure falling to the Vote.

5.8 The **Partners' Council** will advise the Institute through the chair. Specifically this will be through the review of the Annual Report and by the provision of advice to assist the Institute in discharging its functions.

## 5.9 Relations with Parliament

The Secretary of State for Health is answerable to Parliament on all aspects of the Institute's business. However, Members of Parliament, the National Assembly for Wales, Members of the European Parliament and the general public will be encouraged to write direct to the chair or chief executive of the Institute on any matters relating to its day-to-day operations.

## 5.10 **Departmental sponsorship**

The **senior departmental sponsor** (SDS) is the senior point of contact for the Institute within the Department of Health.

The SDS is responsible for ensuring that the Institute operates within the following parameters:-

- the Institute must effectively discharge the functions for which it was established;
- as a public body, the Institute is accountable for the proper use of any public funds and is obliged to operate under government accounting rules to ensure propriety, regularity and value for money.

In particular, the SDS is responsible for the Department of Health's relationships with the Institute, as an arm's length body and for liaison with the National Assembly for Wales.

### 5.11 The SDS will ensure that effective mechanisms are in place for performance management and financial monitoring of the Institute.

The SDS will develop a direct relationship with the chair and chief executive of the Institute.

The SDS will make sure that the chair and chief executive of the Institute are aware of the objectives and priorities of ministers, the Secretary of State for Health and the National Assembly for Wales and are in touch with the Department of Health and the Assembly at a senior level.

### 5.12 The SDS will report annually to the chief executive of the NHS Executive on the performance of the Institute and the systems that are in place to monitor it.

### 5.13 The SDS will appraise the performance of and hold an annual appraisal meeting with the chair of the Institute.

### 5.14 The **departmental sponsor branch** will support the SDS in the management of the relationship with the Institute. In particular the sponsor branch will:

- be the first point of contact and advice for the Institute;
- review the framework document;
- be budget holder for the Institute and monitor the financial performance of the Institute (advised by the finance liaison point);
- support the SDS by conducting the annual accountability review of the Institute and preparing the subsequent report;

- support the SDS by conducting regular performance and financial reviews with the Institute;
- maintain links with the Institute ensuring close liaison about policy developments, targets and financial information;
- manage the process for appointing non-executive board members.

## **6. Planning and Reporting**

### **6.1 Corporate Plan**

The Institute will produce a three year corporate plan updated annually or as directed by the Secretary of State for Health and the National Assembly for Wales.

6.2 By 21 April 2000 the Institute will present its first corporate plan to the Secretary of State for Health and the National Assembly for Wales which will set out the proposed evolution of the Institute over the three year period to 2002- 2003.

6.3 Subsequent corporate plans will be produced by 1 December of the relevant year.

6.4 The corporate plan will include:

- projections of the number of appraisals and guidelines to be undertaken in each of the three years;
- projections on the required capacity and resources of the Institute in each of the three years;
- a broad statement of the objectives of the Institute;
- proposals for improvements in the *efficiency* and *effectiveness* of the operation of the Institute;
- a strategy for continuous improvement of the Institute's internal processes and products to achieve best value;
- a strategy for developing the Institute's impact and standing;
- proposed methods by which the Institute's impact on the quality of care might be assessed;
- the Institute's communications strategy.

6.5 The corporate plan will describe the broad programme of work for the planning period and the manner in which it is to be implemented. It will identify the specific and strategic objectives for the Institute and make the necessary financial forecasts. **It will also make realistic assumptions about the environment within which the Institute operates, identifying relevant economic and policy factors as well as the potential for exploiting new opportunities.** It will draw up alternative strategies on the basis of different assumptions, explaining the consequences for the various programmes and hence overall objectives.

### **6.6 Annual Business Plan**

The chief executive of the Institute will present a proposed business plan by 1 February of each year to the Senior Departmental Sponsor. The business plan will review progress against the targets for the current year and will include :

- objectives and the key performance targets to be achieved over the year including the degree of uncertainty and risk;
- the strategies to be employed to achieve the objectives and improve performance;
- the work programme to be implemented;
- an analysis and forecast of workload;
- forecast income and expenditure, together with a financial profile for the year including forecasts of financial and staffing requirements to meet the anticipated workload;
- identification of priorities within available resources;
- details of any planned changes or known external events which might have a significant impact on its functions, level of business activity or estimated budgetary requirements;
- the proposed budget for administering the different elements of the Institute's work programme and the proposed budget for any additional and/or related tasks required by the Secretary of State for Health and the National Assembly for Wales;

6.7 These proposals, once agreed by the Secretary of State for Health, the National Assembly for Wales and the sponsor branch of the Department of Health, will form the basis for the Institute's cash limit for the following year, which will be accounted for within Class XII, Vote 1.

**6.8** The annual business plan will be published.

**6.9** The Institute will produce and publish an *Annual report and accounts* at the end of each financial year. This report will be submitted to the Secretary of State for Health and the National Assembly for Wales no later than 30 November each year.

6.10 The Institute will discuss the *Annual report and accounts* with the sponsor branch of the Department of Health prior to its publication.

6.11 The annual report will include an analysis of Board members' remuneration and officers' salaries as follows:

- for members : the Chairman's and CE's remuneration separately and expressly itemised; other members remuneration to be listed in the following bands - £0 - £5000; £5,001 - £10,000; and in incremental bands of £10,000 thereafter;
- for officers: in bands equivalent to those for members, excluding Chairman and CE.

6.12 The Institute shall monitor its practice in relation to equal opportunities, prepare equal opportunity policy statements and report thereon to the Secretary of State and the National Assembly for Wales at the end of April each year.

## **7. Performance Management Systems**

- 7.1 The Department of Health, the National Assembly for Wales and the Institute will develop a good working relationship characterised by regular contact and an atmosphere of trust.
- 7.2 Additionally, there will be a series of structured contacts as part of a secure performance management framework.

### **Agreement of the corporate plan, the business plan and targets**

- 7.3 The SDS will agree and approve the corporate plan, the business plan and the Institute's targets.
- 7.4 The business plan will contain annual targets that will be the main tool for judging the Institute's performance.
- 7.5 The setting of these targets and monitoring progress towards achieving them will be a focal point in the relationship between the sponsor branch of the Department of Health and the Institute.
- 7.6 The targets will reflect ministerial priorities and the most important areas of the Institute's work. There will also be targets for the different aspects of the Institute's corporate plan.
- 7.7 The annual targets will involve qualitative as well as quantitative measures and will present a degree of challenge.

### **Formal in-year monitoring of performance**

- 7.8 Although the main responsibility for managing the Institute lies with the body itself, external monitoring by the Department of Health will be an integral part of the management process.
- 7.9 The SDS will, together with the sponsoring branch of the Department of Health and the National Assembly for Wales, hold quarterly meetings with the chair and chief executive of the Institute to review progress against the annual targets and discuss any other issues arising from the Institute's work. These meetings will also be forward looking and will help to inform future budget setting rounds.
- 7.10 The Institute will provide appropriate documentation in advance of these meetings. This documentation will include a report on progress against targets set out in the business plan, exception reports, equal opportunities statistics and brief information on the contracts the Institute has entered into to meet its work programme.
- 7.11 The Institute will provide monthly financial profiles to the Department of Health. These profiles should include an outturn versus planned spending report with a variance analysis and a short narrative outlining the current position explaining any unforeseen pressures or variances.

- 7.12** The Institute will effectively manage the existing projects whose responsibilities transfer to it. The Institute will inform the sponsor branch of the Department of Health when there are any substantial problems with any of the projects. Any changes that affect the aims and objectives of these projects must first be agreed with the sponsor branch of the Department of Health and the National Assembly for Wales.
- 7.13** The sponsor branch will develop routine, informal links with the Institute in order to keep abreast of significant developments that may have resonance for the Department of Health and the National Assembly for Wales. The chief executive of the Institute will alert the sponsor branch of the Department of Health when there are any such developments.
- 7.14** The Sponsor Branch will advise the Institute of the development, within the Department of Health, of any policy initiative that will impact directly on the Institute's affairs.

#### **Annual accountability review**

- 7.15** In addition to the four quarterly monitoring meetings there will be an annual accountability review meeting with the chair and chief executive of the Institute, a representative of the National Assembly for Wales, chaired by the SDS.
- 7.16** Following this meeting there will be an initial meeting between the SDS and the chief executive of the Institute to clear points of detail and agree issues for discussion with the Secretary of State for Health and the National Assembly for Wales.
- 7.17** Then there will be an annual review meeting chaired by the Secretary of State for Health. At this meeting, the management of the Institute will account for the activities and financial performance of the Institute over the past year, in particular its achievements against targets. Any strategic difficulties will also be discussed. This meeting will help to identify topics that will be in the Institute's annual report.

#### **Five yearly Prior Options Review**

- 7.18** The Institute will undergo a fundamental review every five years to decide if the status or remit of the Institute needs to be altered to reflect changing circumstances.

## **8. Finance**

### **Income and expenditure**

- 8.1** The chief executive of the Institute is each year required to contain
- the gross administrative expenditure of the Institute, in cash terms, within a budget agreed as part of the annual business plan;
  - the total gross expenditure of the Institute, in cash terms (including expenditure on any additional functions agreed with the Department) within the cash limit set by the Department, together with sums receivable under the NHS Act 1977 (as amended) and any other income
- 8.2** The Institute will comply with the requirements of the Department of Health accounting practice (as contained in the NHS Manual for accounts) and any other guidance or instructions on financial matters from the Department of Health, the National Assembly for Wales and the Treasury, so far as they are relevant.

### **Accounting systems**

- 8.3** The Institute or its agents will maintain financial information on
- the annual accounts of the Institute expenditure including that on administration, organisation and on the production and dissemination of appraisals, assessments and guidelines, on a cash flow basis.
- 8.4** A set of the Institute's accounts will be included in the Institute's annual report to Parliament.
- 8.5** The Accountable Officer is responsible for ensuring that adequate management and accounting systems are in place to meet the Institute's objectives. This should include the ability to
- monitor regularly all aspects of the Institute's expenditure against budget;
  - produce annual financial forecasts and accounts as required by the Secretary of State and the National Assembly for Wales.

### **Capital Assets**

- 8.6** The Institute will maintain a register of all of its tangible capital assets valued at £5,000 or more and will be responsible for their annual revaluation on a current cost basis and for accounting for them through depreciation charges in the financial accounts of the Institute.
- 8.7** Funding for capital investment, if any, will be considered within the framework of an approved investment programme included in the Corporate and Business Plans.

- 8.8 Individual projects will be evaluated using standard Government investment criteria (NHS Capital Investment Manual). Capital charges will be payable on any such funding.

### **Financial delegations**

- 8.9 In advance of the start of each financial year, the Department will send the Institute a formal statement of its financial provision, as approved by the Secretary of State, together with a statement of any policy changes affecting the Institute in the coming financial year. The notified provision is subject to Parliamentary approval and will form part of the Department's overall expenditure limit.
- 8.10 Taking account of its notified provision, the Institute will prepare a budget of estimated payments and receipts, including a profile of expected expenditure and grant-in-aid. This budget will be part of its annual business plan (see Section 6.6)
- 8.11 Subject to the Secretary of State's approval of the budget, the Institute has authority to incur approved budget expenditure without further reference to the Department on the following conditions:
- the Institute complies with the delegations set out in Annex E of this document. These delegations may not be altered without the prior agreement of the Department
  - inclusion of any planned and approved expenditure in the Institute's budget does not remove the need to seek formal Departmental approval where any proposed expenditure is outside the delegated limits or is for new plans not previously agreed
  - the Institute provides the Department with information about its operations, performance on individual elements of its work programme or expenditure as the Department may reasonably require
  - the Institute provides immediate, formal, notification to the Department where it becomes apparent (at any time) that there is likely to be an overspend of its expenditure (as voted by Parliament) over the year
  - the Institute notifies the Department, as soon as possible, if it is likely to under spend its total grant in aid by more than the equivalent of 2 per cent

## **8.12 The Institute will also provide the Department with**

- a monthly financial statement showing, for each main budget heading, the payments made and any receipts received in the preceding month. It should also show the accumulated net payments to date and the balance of cash available for the year
- a monthly analysis of financial outturn against income and expenditure forecasts, indicating proposed action where necessary

8.13 The chief executive of the Institute will ensure that the conduct of the Institute complies with Standing Orders and Standing Financial Instructions formally adopted by the Institute. The chief executive of the Institute will ensure that these documents are supplemented by written procedure notes for each member of staff employed on duties involving the finances of the Institute.

## **Banking**

8.14 The chief executive of the Institute is responsible for ensuring that the Institute's banking arrangements are in accordance with the requirements of Government Accounting (NHS manual of accounts) and are carried out efficiently, effectively and economically.

8.15 The Institute will ensure that these arrangements are suitably structured, represent value for money and are reviewed at least every two years.

## **Internal Audit**

8.16 The Institute will be responsible for making arrangements for internal audit. It is recommended that one of the non-executive members should be specifically given the task of overseeing the internal audit process.

## **External Audit**

8.17 External audit will be by auditors appointed by the Audit Commission. The annual number of audit days will be agreed between the Institute and the Commission.

## **9. Review of the Framework Document**

- 9.1 The framework document will be reviewed by the Department of Health and the National Assembly for Wales, in consultation with the Institute, every three years. Any necessary amendments will be made by the Department of Health and the National Assembly for Wales and agreed by the Institute and the Treasury.
- 9.2 The Secretary of State, the National Assembly for Wales or the chair of the Institute may propose modifications to the Framework Document before the three year review if these appear necessary in the light of experience or to take account of changed circumstances.

## **Annex A**

### **Directions to the National Institute for Clinical Excellence**

#### **NATIONAL HEALTH SERVICE ACT 1977**

##### **Directions to the National Institute for Clinical Excellence**

The Secretary of State for Health and the National Assembly for Wales, in exercise of powers conferred by sections 11, 13, 17 and 126(4) of the National Health Service Act 1977<sup>(1)</sup>, article 3 of the National Institute for Clinical Excellence (Establishment and Constitution) Order 1999<sup>(2)</sup>, regulation 9 of the National Institute for Clinical Excellence Regulations 1999<sup>(3)</sup> and of all other powers enabling them in that behalf, hereby give the following directions:-

##### **Application, commencement and interpretation**

- 1.-(1) These Directions are given to the National Institute for Clinical Excellence.
- (2) These Directions shall come into force on the date after the date on which they are made.
- (3) In these Directions:-

"the Institute" means the National Institute for Clinical Excellence.

##### **Functions of the Institute**

- 2.-(1) The Secretary of State and the National Assembly for Wales direct the Institute to exercise the following functions –

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<sup>(1)</sup> 1977 c.49.  
<sup>(2)</sup> S.I.1999/220.  
<sup>(3)</sup> S.I.1999/260.

- (a) to appraise the clinical benefits and the costs of such health care interventions as may be notified by the Secretary of State or the National Assembly for Wales and to make recommendations;
  - (b) to develop guidelines providing advice on good practice in the management of such diseases and conditions as may be notified by the Secretary of State or the National Assembly for Wales;
  - (c) to develop methods of clinical audit for the review of clinical care in relation to such matters as may be notified by the Secretary of State or the National Assembly for Wales;
  - (d) subject to the approval of the Secretary of State and the National Assembly for Wales, to disseminate, as appropriate and via an appropriate range of media, such recommendations, guidelines and audit methods throughout the NHS (including to NHS bodies, health service professionals, the Department of Health and the National Assembly for Wales) and to the general public;
  - (e) to look into and consider, for the purpose of advising the Secretary of State and the National Assembly for Wales with regard to possible improvements in the provision of health services and in the effective use of available resources, such other matters as may be notified by the Secretary of State or the National Assembly for Wales.
- (2) In addition to the functions described in paragraph (1) above the Institute may, subject to the approval of the Secretary of State and the National Assembly for Wales–
- (a) consider and, as appropriate, endorse guidance prepared by other bodies concerning the clinical benefits of health care interventions and good practice in the management of diseases and other conditions affecting health;
  - (b) itself develop methods of clinical audit for the review of clinical care.

- (3) In exercising the functions described in paragraphs (1) and (2) the Institute shall have regard to the following factors -
- (a) the broad clinical priorities of the Secretary of State and the National Assembly for Wales (as set out for instance in National Priorities Guidance and in National Service Frameworks, or any specific guidance on individual referrals);
  - (b) the degree of clinical need of patients with the condition or disease under consideration;
  - (c) the broad balance of benefits and costs;
  - (d) any guidance from the Secretary of State or the National Assembly for Wales on the resources likely to be available to the NHS and any guidance from the Secretary of State or the National Assembly for Wales on such other matters as they may think fit;
  - (e) the effective use of available resources.

### **Appointment of Committees**

3. The Secretary of State and the National Assembly for Wales direct the Institute to appoint, in accordance with regulation 9 (1) of the National Institute for Clinical Excellence Regulations 1999, the Committees to be known as the Partners Council and the Appraisal Committee.

## **Appeals arrangements**

4. The Secretary of State and the National Assembly for Wales direct the Institute to make arrangements for holding appeals, on the application of persons aggrieved by recommendations made by the Institute under article 2(1)(a), on the grounds that the Institute has failed to act fairly, has exceeded its powers or has acted perversely in the light of the evidence submitted.

## **Annual and other reports**

5. The Secretary of State and the National Assembly for Wales direct the Institute –
  - (a) to produce an annual report on the Institute's activities and finances (including officers' remuneration) and to submit it to the Secretary of State and the National Assembly for Wales no later than 30 November each year;
  - (b) to produce and submit to them each year the report mentioned in article 6(b) below.

## **Equal Opportunities**

6. The Secretary of State and the National Assembly for Wales direct the Institute to attach particular importance to equal opportunities issues both as an employer and in relation to the guidance it issues.

In particular the Institute shall-

- (a) prepare equal opportunity policy statements;
- (b) monitor its practice in relation to equal opportunities and report thereon to the Secretary of State and the National Assembly for Wales at the end of April each year.

## **Conduct of Business**

7. The Secretary of State and the National Assembly for Wales direct the Institute to carry out its functions having regard to the matters specified in the Protocol annexed to these Directions.

Signed by authority of the National Assembly for Wales

August 1999

A Member of the Senior Civil Service,  
National Assembly for Wales

Signed by authority of the Secretary of State for Health

August 1999

A Member of the Senior Civil Service, Department of Health

## **Annex to the Directions**

### **1. Quality**

The Institute will aim to work to the highest standards of quality in all its activities; in particular:

- to use the resources which it is allocated in the most effective way possible to achieve optimum value for money for high quality outcomes;
- to conduct its business in a way which gains the respect of the National Health Service, health professionals, related industries, the Department of Health, the National Assembly for Wales, patients and the public;
- to deal with all appointments with due regard to equal opportunities and best personnel practice;
- to devise and implement effective systems of corporate governance.

### **2. Openness and Accountability**

The Institute will aim to abide by the provisions of relevant Codes of Conduct and Accountability, published by OPCA.

The Institute will endeavour to conduct its business in an open and transparent manner.

### **3. Working In Partnership**

The Institute will aim to build and maintain effective working relationships with the National Health Service, the NHS Information Authority, the Department of Health, the National Assembly for Wales, bodies representing the health professions, health related industries and patient and user groups.

## **Annex B**

### **Development and dissemination of clinical guidelines and audit methodologies**

1. Guidance from the Institute will include guidelines for the management of certain diseases or conditions and, where appropriate, it will cover all aspects of the management of that condition – from prevention to self-care through primary care, secondary care and more specialist services.
2. The Institute will undertake, commission, adopt, adapt, and disseminate guidelines on the basis of a work programme set by the Department of Health and the National Assembly for Wales in consultation with the Institute.
3. The Institute may wish to propose topics for inclusion in its work programme. These topics must first be agreed with the Department of Health and the National Assembly for Wales.
4. The Institute will ensure that its guidelines meet the highest possible standards with respect to clinical and cost effectiveness. The Institute will develop, consult on and publish standards for guidelines and will apply these to its programme of work. These standards will be agreed with the Department of Health and the National Assembly for Wales.
5. All guidelines will contain audit methodologies and, where appropriate, guidance on GP referrals.
6. The Department of Health, in consultation with the National Assembly for Wales, may ask the Institute periodically to review certain guidelines. Guidelines which are reviewed will have to meet the same standards as new guidelines.
7. The Institute will follow a transparent and well-structured process for the construction of its guidelines, giving appropriate interested parties the opportunity to submit evidence and to comment on the draft conclusions.

### **Dissemination of clinical guidelines**

8. The Institute will effectively disseminate clinical guidelines and audit methodologies by working in partnership with the national professional bodies, the Department of Health, the National Assembly for Wales, the NHS and the public.

## **Annex C**

### **Appraisal of health interventions**

This memorandum sets out the ground-rules under which the Institute will carry out the appraisal of individual health interventions, in order to promote the appropriate use of those which offer good value to patients and to discourage the use of those which do not. It builds on the proposals set out in the discussion paper *Faster access to modern treatment*, modified in the light of comments received and further discussion with stakeholders. Further details are available from the Institute.

#### **Selection of interventions for referral to the Institute**

The responsibility for determining which interventions should be referred to the Institute will remain with the Department of Health, in consultation with the National Assembly for Wales, the Institute and other interested parties. Once the process is mature, the Department of Health will aim to give final notification of referral of interventions to the Institute no later than 9 months before the point at which guidance is to be ready for dissemination. Exceptionally, a shorter notice period may be necessary, for instance when a technology is changing rapidly or when new evidence radically alters the perception of an existing technology.

#### **Submission of evidence**

3. The Institute, in consultation with the Department of Health, will identify the "sponsor(s)" of the technology (if any) and any appropriate NHS, professional and patient groups with an interest and invite them to submit evidence. Where there is no commercial sponsor the Department will on behalf of the Institute commission any necessary research from a suitable independent person or organisation.
4. The contents of the evidence package to be submitted will be determined by the Institute, in consultation with interested parties. The Institute should aim to apply equal rigour to its appraisal of all types of intervention.
5. The Institute will need to give careful thought to issues of confidentiality. As a general principle, The Institute's processes should be as transparent as possible and it is highly desirable that the evidence underlying its recommendations should be accessible (see para 15 below). However, to operate effectively it will wish to have access to information from sponsors which is not yet in the public domain at the point of appraisal. In many cases, this information will be commercially confidential and sponsors will be reluctant to make it available unless they can be assured that it will not be disclosed outside the Institute.
6. The Institute will adopt policies which reflect these objectives, subject to current legal requirements (including any future freedom of information legislation) and prevailing understandings between government, industry and the general public on information in regulatory submissions.

## **Appraisal process**

7. The Institute will follow a transparent and well-structured process for its appraisals, giving appropriate interested parties the opportunity to submit evidence, to comment on draft conclusions, and to appeal to a panel independent of those involved in the original judgement in cases where the Institute is alleged to have failed to act fairly, to have exceeded its powers or to have acted perversely in the light of the evidence submitted. During the early years of the process, the Institute will be expected to respond sympathetically to requests from interested parties to accept the results of modelling studies in the absence of data derived directly from clinical trials, where the need for such data could not reasonably have been foreseen. The current form of this process is set out in the Institute's "Interim Appraisal Guidelines" which are available on request from the Institute. If it becomes necessary to modify this process in the light of experience, the Institute will consult on proposed changes and will give due notice of bringing them into effect.

## **Timescale**

8. It is intended that the whole process should be completed as expeditiously as is consistent with allowing for all parties a reasonable opportunity to make their input. In particular, for new technologies, the intention is that guidance should be available to the NHS as soon as possible after the launch or general dissemination of the technology. The process (as described in Appendix C of the Institute's guidance document) would imply an overall timetable of up to 8 months from submission of evidence to issue of guidance.
9. In exceptional circumstances, for instance in the case of a review of previous guidance in the light of significant new evidence, this timetable may be abbreviated provided that interested parties still have a realistic opportunity to be consulted.

## **Appraisal methodology and criteria**

10. The Institute's function in relation to appraisals, as set out in Directions issued by the Secretary of State for Health and the National Assembly for Wales, is "to appraise the clinical benefits and the costs of such health care interventions as may be notified by the Secretary of State or the National Assembly for Wales and to make recommendations;". In other words, its task is to assess the evidence of all the clinical and other health-related benefits of an intervention – taking this in a wide sense<sup>4</sup>, to include impact on quality of life, relief of pain or disability etc as well as any impact on likely length of life – to estimate the associated costs, and to reach a judgement on whether on balance this intervention can be recommended as a cost-effective use of NHS and PSS resources (in general or for specific

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<sup>4</sup>The wider benefits of treatment (such as a reduction in disability which allows continuation of employment) can be taken into account on the benefit side of the equation but should not simply be treated as an offset on the cost side.

indications, subgroups etc). Where there is already an intervention for the condition, the appraisal should appraise the net impact on both benefits and costs of the new intervention relative to this benchmark.

11. In reaching this judgement the Institute should have regard to those factors listed in Directions issued by the Secretary of State for Health and the National Assembly for Wales, namely:
  - i the broad clinical priorities of the Secretary of State and the National Assembly of Wales (as set out for instance in National Priorities Guidance and in National Service Frameworks, or any specific guidance on individual referrals),
  - ii the degree of clinical need of the patients with the condition or disease under consideration,
  - iii the broad balance of benefits and costs,
  - iv any guidance from the Secretary of State or the National Assembly for Wales on the resources likely to be available and on such other matters as they may think fit;
  - v the effective use of available resources.

The Institute will also wish to ensure that, in carrying out its statutory functions, it is sympathetic to the longer-term interest of the NHS in encouraging innovation of good value to patients.

12. The Institute will develop a detailed methodology for its appraisals, consistent with guidance given to it by the Department of Health , and taking as its starting point the proposals in *Faster access to modern treatment*. The Institute should consult with its stakeholders over this methodology and over any future changes. The Institute will liaise closely with the Joint Committee on Vaccination and Immunisation and with the National Screening Committee to ensure that their respective methodologies are as far as relevant consistent with one another.

#### **Format and contents of the Institute's guidance**

13. The Institute will produce guidance to commissioners and clinicians on the appropriate use of the intervention alongside current best practice. This guidance should among other things cover the following aspects:
  - i an assessment of whether or not the intervention can be recommended as clinically effective and as a cost-effective use of NHS resources for NHS use, either in general or in particular circumstances (first or second line treatment, for particular subgroups, for routine use or only in the context of targeted research etc);

- ii where appropriate, any priorities for treatment;
  - iii recommendations on any questions requiring further research to inform clinical practice;
  - iv an assessment of any wider implications for the NHS;
  - v a concise summary of the reasoning behind the Institute's recommendations and the evidence considered , with a supporting paper available on request.
14. The Institute will also when appropriate prepare guidance for users and carers, consulting with appropriate patient groups on the best format and means of dissemination. This guidance should *inter alia* explain the nature of the clinical recommendations, the implications for the standards which patients can expect, and the broad nature of the evidence on which the recommendations are based.
15. As far as practicable all evidence sources should be made available for inspection.

#### **Legal status of guidance**

16. All guidance must be fully reasoned and written in terms which makes clear that it is guidance. Guidance for clinicians does not override their professional responsibility to make the appropriate decision in the circumstances of the individual patient, in consultation with the patient or guardian/carer and in the light of any locally agreed policies. Similarly guidance to NHS trusts and commissioners must make clear that it does not take away their discretion under administrative law to take account of individual circumstances.

#### **Implications for guidelines and other information**

17. Where appropriate, the Institute will ensure that the implications of its recommendations are carried through to
- i related clinical guidelines,
  - ii PRODIGY guidelines,
  - iii the National Electronic Library for Health,
  - iv the protocols used by NHS Direct and NHS Walk-in Centres, and
  - v any material for patients produced by NHS Direct Online.

#### **Review of guidance**

- 18 The Institute will make arrangements to keep its appraisal guidance under review. In addition, it will make arrangements to consider requests from interested parties to review extant guidance in the light of significant changes in the evidence base, where these are likely to have a material impact on the guidance.

## **Annex D**

### **Communications strategy**

1. The Institute will develop a proactive communications strategy that will be included in the Institute's corporate plan and will be agreed with the Director of Communications of the Department of Health.
2. The communications strategy will indicate how the Institute will build formal and informal links with the Department of Health, the National Assembly for Wales and other stakeholder organisations.
3. The Institute will draw up a strategy for disseminating clinical guidelines and audit methodologies and will develop a system for communicating this information to all interested parties (including patients and the public). The timing of the announcements will be co-ordinated with the Department of Health to ensure that they are as effective as possible.
4. From the outset, the Institute will implement an effective bilingual policy in its public business in Wales. It will have regard to the Guidelines issued by the Welsh Language Board and approved by Parliament in 1996. On receipt of a notice from the Welsh Language Board, the Institute is required by law (Welsh Language Act 1993) to prepare and implement a statutory Welsh Language Scheme.

## **Annex E**

### **Conditions on the Institute's funding**

1. The Institute has delegated authority to:
  - (a) Approve and certify all expenditure relating to appraisals, assessments and guidelines;
  - (b) Authorise expenditure, provided that expected net spending for the current year does not exceed the cash limit for the Institute agreed each year by the Department of Health;
  - (c) Accept receipts without limit;
  - (d) Make special payments not exceeding 5% of the Institute's total pay bill in that year, as performance awards to staff of the Institute;
  - (e) Negotiate, organise and review money transmission arrangements with Banks, which are members of the inter-bank payment clearing system;
  - (f) Approve any management contracts by competitive tender, following EU procedures as necessary; except that single tender approach may be used for any one contract of up to £50,000 in total;
  - (g) Approve and certify payment for capital acquisitions, other than information technology (IT) equipment, with a value in excess of £250,000 provided that a minimum of three quotations have been sought by means of a competitive tendering exercise;
  - (h) Approve IT proposals up to a limit of £50,000 per project (including all project costs); a minimum of three quotations will be sought wherever practicable;
  - (i) Make special payments (as defined in Government Accounting) of up to £50,000 for any individual claim as compensation, including payments to staff for loss of personal effects, except in the case of payments made under legal obligation where the limit is £100,000 plus costs;
  - (j) Make payments up to £50,000 per claim in respect of losses of cash including overpayments of salaries and wages, fees and charges, fruitless payments and bad debts.
2. Subject to the consent of the Department of Health, the chief executive shall ensure that the Institute **does not**:
  - (a) make loans or gifts of money or grant-supported assets;
  - (b) have a bank overdraft or borrow money at any time;

- (c) give guarantees, indemnities or letters of comfort, etc or incur any other contingent liability (whether or not of a legally binding form) except
- when a liability is of a standard type which is given in the course of normal commercial business dealings,
  - for indemnities to non-executive members against personal liability for advice given in good faith on Institute business; but this must only be in the form from time to time approved by the Treasury for this purpose.
  - charge any asset or security.
3. The chief executive shall ensure the Institute keeps a record of all losses and special payments, whether within delegated powers or not, and all losses sustained or special payments made shall be suitably recorded in the statement of accounts for each financial year. A record of gifts given and received should also be kept.
  4. The chief executive shall ensure that the Institute does not undertake any insurance without prior approval of the Department of Health.
  5. The Institute may give authority to the chief executive for sub-delegation of the powers shown above to named staff of the Institute.