

UK PRIMARY IMMUNODEFICIENCY NETWORK

STANDARDS AND EXPLANATORY GUIDANCE

**For accreditation for PID centres and
Home Immunoglobulin Programmes**

Introduction

Introduction to UKPIN PEER REVIEW ACCREDITATION SCHEME

The UK Primary Immunodeficiency Network peer review accreditation scheme was set up as a direct result of the findings of the National PID Audit funded by the Department of Health. It has been developed to enhance diagnosis, care and management for patients with primary immune deficiencies. PID services are evaluated against consensus standards set by the profession at an open meeting in October 2000. The process includes initial self-evaluation, followed by external peer review by means of an assessment visit by trained assessors. Considerable emphasis has been put on the opportunity for nurses and clinicians to share ideas as well as collection and consideration of the views of patients and managers.

The scheme is voluntary at present. Application is made to the UKPIN office on a standard form (*which will be available to be downloaded from the UK-PIN web site in 2003*). This form requires details of basic departmental statistics and facilities, such as staffing levels, patient numbers, particular patient groups, facilities and diagnostic assays available. There is a list of standards relating to these topics against which the centre will be assessed when visited; assessors will need to see the evidence that the department complies with the standards. Completion of the form enables the applicant unit to consider its own services in detail through the self-evaluation, what is required to meet the standards and to outline how it would like to develop the service. Guidance is given in this manual for interpretation of each standard, though each centre is assessed individually at the visit.

A process for collecting patient views via the patient organisation – the Primary Immunodeficiency Association [PiA] is included. Informal discussions will also be held with patients in the centre on the day of the visit by the assessors.

UKPIN Assessors, including consultants with previous training in accreditation procedures by Clinical Pathology Accreditation [CPA] and senior nurses, have undergone assessment training and are conversant with the standards. Three training days have been held and there are now 10 nursing & 11 medical assessors who have been fully trained; further training days for new assessors are being held annually.

An assessment team is allocated by UKPIN; each team consists of 2 consultants (one of whom is usually CPA trained) and a senior nurse, and is led by the experienced assessor. Once more experience has been gained; it may be possible to use only 2 assessors (1 senior nurse and 1 consultant). Individuals are selected from a different geographical region and visit the centre under review for 2 days. They receive the department's application form prior to the visit to enable them to consider the type of evidence required to demonstrate compliance. Evidence provided in the initial application reduces the need for data collection at the visit, leaving time for observation and exchanges of ideas. The views of patients, collected anonymously by the PiA on a standard form with the help of the centre, are available to the assessors

to share with the centre at the visit. Interviews with appropriate managers enable realistic evaluation of any proposed developments, as well as a chance to discuss any deficiencies that may need correction.

Visits are rounded off by a “debriefing meeting” between the assessors and the department’s management team at the end of the visit. The purpose of this is to discuss the findings with the centre before leaving the site; such a briefing enables any misunderstandings to be corrected immediately.

Following the visit, the assessors prepare a detailed report on the centre, highlighting the areas of excellence and any perceived weaknesses. The report is considered by the PIN Accreditation Standing Advisory Committee for consistency between centres and once approved, is sent to the lead clinician in the reviewed centre; in the future a copy of the report will also go to the Chief Executive of the host Trust.

So far the scheme has proved to be most beneficial to the visited centre, raising awareness of PIDs in the host Trust, highlighting any deficiencies in terms of facilities or staff and providing a process for detailed consideration of patients’ views.

After the visit, the process is reviewed by means of questionnaires about the visit to both the assessors and the staff in the visited centre. A follow-up questionnaire is also being devised, to be used 1 year later, to document progress of the centre towards full compliance since the visit.

There is currently no charge for this process as pilot funding has been generously provided by BPL, though this will have to be reviewed. UK PIN will charge an appropriate fee to cover the costs of the inspection, and an annual registration fee for accredited Centres. Information on the fees will be made available on the website at the time of application

Standards A: Organisation and Administration

A1 Organisation of Centre

To set the back ground for the Centre
Structure and mix of skills for management at all levels
Line management of all types and grades of staff

Look at: *written brief information about the Centre; the service organisation, staff roles, types of service provided (see also D6)*

A2 Appropriate caseload

Not too many to be safe
Enough to maintain appropriate skills

Look at:

1. *Sessional commitment of staff – consultant, nursing and trainee*
2. *Numbers of clinics devoted to PID*
3. *Case mix: suspected /defined / follow up*
4. *Time given to associated centres*

A3 Process for defined management

Process for appropriate funding
Gaining experience and documentation of new methods etc ie CPD
Communication with other centres for updating

Look at: *minutes of meetings for management, finance managers & regular meetings with patient representatives inline with Trust policy*

A4 Adequate funding & budgetary management

Funding should include the staff salaries
Capital and revenue consequences of home therapy
Provision of infusion pumps
Travelling costs for home visits
Plans to cover patients if /when Ig is restricted

Look at:

1. *Evidence of bid for staff if staff numbers are too low*
2. *Budget sheets to show development monies are forthcoming*
3. *Income sheets to show that service is sustainable especially for all immunotherapies (γ interferon, immunoglobulin, cytokines, monoclonal antibodies etc)*
4. *Activity data re patients, infusions, pumps*
5. *For soft-funding of staff, a written agreement that the Trust will take on the revenue consequences of the programme when the soft funding ends*
6. *Responsibilities of and involvement of managers and CEO at interview*

Standards B: Staffing

B1 Appropriately experienced consultants

Minimum of 5 years experience in management of patients with PID ie CCST in Immunology or Paediatric Infectious Diseases & Immunology or equivalents
For children, involving either a specifically trained paediatric consultant /s or in conjunction with such an individual
Proportion of time spent on PID (see A2 case load)
Deputising arrangements
Appropriate resuscitation course

Look for:

1. *Appropriate training/ secondment [perhaps for equivalent of one year F/T for training pre or post appointment] ie look at consultant's cv*
2. *Substantial clinical experience of patients referred for suspected PID*

B2 Appropriately experienced nurses

Grade G or above / equivalent for Head nurse
Deputising / cover arrangements
Deputy would normally be a grade F
Deputy from another speciality only if appropriately trained
ENB998/ City & Guilds 7307 teaching certificate or equivalent experience is currently a requirement.

Look for:

1. *Competences +/- evidence of PID experience in portfolios*

B3 Skilled cover available out of hours

Consultant cover for patients 24 hours as per local arrangements
Nursing cover in office hours

Look for:

1. *Policies +/- rotas; arrangements for emergency admissions & advice should be clearly documented, including the mechanism by which calls from home therapy patients will be transferred to the Centre providing cover*

B4 Paediatric trained immunologist/ nurse if children are involved

Policies for adolescents' transfer arrangements

Look for:

1. *Evidence of training/ considerable experience with children,*
2. *Involvement of either a specifically trained nurse in paediatrics or in conjunction with such an individual*

B5 Recognition for postgraduate training if appropriate

Posts are registered with JCHMT. Training programmes must include specific training in the diagnosis and management of PID

Look for:

1. *SpR training programme for JCHMT & last inspection report*
2. *Talk to spRs*

Standards C: Facilities

C1 OPD & inpatient facilities for diagnosis & management

Regular outpatient clinics for assessment and follow-up shall be held separately for both adults and children.

Look at:

1. *Inpatient pathways of care*
2. *Talk to staff responsibilities of consultants / spRs/ nurses in outpatients & wards*
3. *Protocols for inpatient care in appropriate services (chest ward, gastroenterology, etc)*

C2 Support from other specialties

Appropriate services such as respiratory medicine, gastroenterology, ENT, infectious diseases, paediatrics, clinical genetics, rheumatology, available

Look at:

1. *Protocols for referring to other specialties (see also D1)*
2. *Evidence in patients' notes of co-operation*

C3 Diagnostic services available

See also application form

Includes radiology and genetics +/- tissue typing

Laboratory services will have CPA accreditation or equivalent.

Look for:

1. *Evidence of satisfactory support from accredited laboratories [Immunopathology, Microbiology, Haematology, Biochemistry, Histopathology, Cytology, Genetics]*
2. *Radiology [HRCT, MRI]*

C4 Facilities for hospital infusions

Appropriate clinical space needs to be adequate in relation to the number of patients treated,

A safe working environment for staff,

Appropriate levels of privacy to patients.

May include facilities for reconstitution of IVIg and storage

Availability of refreshments for patients in appropriate facilities

Maintenance of equipment

Appropriate medical equipment eg auroscopes

Pharmacy ability to cope with products for immunological therapies and good documentation of dispensing to individual patients

Facilities would need to be available for patients unwell during an infusion

Look for:

1. *Areas of outpatients or day case areas provided*
2. *That there is adequate space*
3. *Areas for private consultation with the patients*
4. *Infusion materials - lockable cupboards for consumables*
5. *Information leaflets available (see also E4)*

C5 Office space & A&C staff

Phones and access to fax

Computers and access to PAS, email, web and Intranet

Satisfactory working environment for all grades of staff including trainees, nurses, A&C staff

Look for: office space complies with norms for occupancy for nurses and doctors

C6 Arrangements for hospital based follow-up

OPD arrangements for follow up

Facilities for blood sampling

Facilities for nurse follow-up

Look for:

- 1. Evidence in clinical notes of multidisciplinary reviews*
- 2. Letters to G.P.s*
- 3. Records of follow up letters in the hospital notes (see also D1)*
- 4. Organisation of office to provide notes at appropriate times*

C7 Library and IT facilities

Hospital policies

Storage of journals

Backup for computers

Backup for databases

Look for:

- 1. Access to medical and nursing journals,*
- 2. Literature search facilities*
- 3. Ask about support from IT Department to maintain computer systems.*

Standards D: Clinical Care

D1 Clinical care for patients

Protocols for diagnosis and treatment are being followed

Look for:

1. *Protocols for referral from other services and G.P.s*
2. *Evidence of second opinion if appropriate;*
3. *Evidence for co-operation with the Supra-Regional SCID BMT Units*
4. *Nursing protocols and guidelines for independent practice*

D2 Clinical care for individual types of PID diseases

There should be protocols for the management of individual immunodeficiencies that conform to national and international models [where available], and are applicable to local services..

Protocols should include a comment relating to development for local services

Look for:

1. *Protocols for Management of individual PIDs:*

D3 Disease related PID literature available -

There should be written literature on primary immunodeficiencies

Available both for patients and healthcare workers ie other hospital doctors, GP's, Nurses etc

Look for:

1. *Understandable, up-to-date appropriate literature from the PiA on display in clinic area.*
2. *Copies available in office or from PiA Office.*
3. *Locally derived disease related information, especially for children's clinics*
4. *Regular overview of material*

D 4 Regular monitoring of all immunodeficient patients is documented

Look for:

1. *Evidence of nursing review (see also C6)/ minutes of review meetings*
2. *Regular submission of logs if clinically required*
3. *Documentary evidence of Departmental policies regarding follow-up*
4. *Audit of outcomes*
5. *Organisation of recommended investigations such as lung function testing.*
6. *Evidence of decisions in notes*
7. *Up-to-date follow up spread sheets for radiology, pathology & lung function test results*
8. *Protocols for patients receiving care in local hospitals ie care pathways*
9. *Audit of use of care pathways in outlying hospitals*
10. *Patient held records if used*

D 5 The Centre shall maintain a local database of primary immunodeficient patients and participate in the National UK Register, [& hence the European Immunodeficiency Register].

A minimum data set or database of primary immunodeficient patients, in line with the new requirements for the UK register when available

Databases should be registered under the data protection legislation

Look for:

1. *Pages from local database or UK Register*
2. *Participation in UK Home therapy Register & SCIg Register (if still separate)*
3. *European registers for specific diseases if participating (CD40LD, WAS, etc)*

D 6 A prospectus should be available describing the Centre's services and indicating how patients and other healthcare workers may access services

A brief document indicating the services provided [frequency and location of outpatient and infusion clinics, mechanisms for referrals, contact telephone numbers and fax/e-mail addresses

It should describe the Centre's services and indicating how patients and other healthcare workers may access these.

Look for:

1. *Evidence of use by other specialties*
2. *Display on the Hospital's Intranet*
3. *Updated and document controlled Management Pathways*
4. *Policy for moving to Home Therapy Treatment*

D 7 Patient's notes must be properly maintained, including therapeutic records

Documentation of blood product data is essential.

Look for:

1. *All entries into clinical notes, including documentation of verbal communication, should be signed and dated, with the name & grade in block letters.*
2. *Check Ig product name and dose*
3. *Check all lot numbers (either in notes /Pharmacy/nurses' records) to enable identification of individual patient risks*
4. *Check in pharmacy that blood products ordered on a prescription form acceptable to the Trust (see also nurses' prescribing policy)*

D 8 Specimens shall be archived to enable 'look-back' in cases of suspected blood borne infection.

Look for:

1. *Liase with the Immunology laboratory to check*
2. *A Protocol for Saving Serum from all Ig therapy patients in line with clinical governance*
3. *Policy for retrieval (reasons for, how long to store, where, etc and check it is implemented)*

D 9 There shall be evidence that a risk assessment has been undertaken for every PID patient.

Giving reasons for therapeutic intervention,
Evidence that benefits and risks considered and discussed with the patient and communicated to the GP & reviewed appropriately

Look for:

1. *Summary of the evidence supporting diagnosis,*
2. *Information recorded in the case notes,*
3. *Updated if risks (eg treatment or diagnosis) changed*

D 10 There shall be evidence for patient assent to treatment for every PID patient.

Evidence that the risks and benefits have been discussed with the patient / family in an appropriate fashion

Standards E: Home Therapy

Only relevant if the centre is applying for accreditation as a Home Therapy Centre; if not please move to Section F.

E 1 There are appropriate facilities available for undertaking the home therapy training as necessary

These shall include:

- A separate room for training for privacy
- Room for practice of procedures including venepuncture

E 2 Appropriate support for caseload of patients infusing at home

- Not too many to be safe
- Sufficient experience to monitor safely ie enough to maintain appropriate skills

Look at:

- Evidence that follow up is done ie medical and nursing review*
- How many patients trained in last 2 or so years*
- If done in conjunction with another centre - policy and protocols for training and follow-up*
- Arrangements for training and follow-up*
- Clinics devoted to home therapy follow-up*
- Case mix: suspected /defined / follow-up*

E 3 Home Therapy Training following National Guidelines

- Evidence that the home therapy-training programme is organised according to the nationally agreed guidelines [*The organisation should conform to the agreed guidelines, approved by ACP, Royal Colleges and the Department of Health*].
- A written local protocol of shared care outlining responsibilities for all healthcare workers involved
- Local information for the Home Therapy service is available
- Policy for the use of Immunoglobulin at home

E 4 Documentation is completed indicating consent of patient, GP and funding agency for home treatment

- Patients should continue to comply with criteria for inclusion in programme
- Policy for Information given to patients before starting Immunoglobulin Therapy

Look for:

1. *Information Leaflets*
2. *Shared Care Protocol (see also E2)*
3. *Policy for the use of Immunoglobulin at home (see also E2)*
4. *Disease Related Information (see section D3)*
5. *Documentation is completed indicating consent of patient and GP for home treatment*

E 5 Patients and carers are given necessary training, successful training being documented by completion of model test paper and supervised treatments

Documentation of training as per Guidelines

Look for:

1. *Test paper*
2. *Ask patients about their training*

E 6 There are facilities for assessing appropriateness of infusions at home

Look for:

1. *Departmental policies regarding follow-up, nursing review*
2. *Regular monitoring of all immunodeficient patients*
3. *Regular reassessments of patients competencies*
4. *Check List for Follow-up*
5. *Home Therapy Monitoring sheet*
6. *Home Therapy Assessment Form*
7. *Safety of staff in visits*

E 7 Regular monitoring of all home therapy patients is documented, with regular reassessments of patient competencies for those on home treatment programmes.

Evidence of clinical review eg OPD list

Nursing review eg revision of use of Epipen (if still used) etc

Regular submission of logs

If clinically required, regular submission of diaries

Organisation of recommended investigations such as lung function testing

Home visit records

Requirements for Epipens will be reviewed.

Look for:

Evidence of health monitoring (diaries), medical complications (OPD), blood monitoring (flow charts), competencies (home visits)

E 8 The Centre shall maintain a database of home therapy patients and participate in the National Home Therapy Register scheme

Local PID Database

IVIg Home Therapy Register & S/C Home Therapy Register (*if still separate from UK register*)

Standards F: Audit, Education & Management

F 1 Regular audit, internal/external

There is evidence of regular audit [internal and external].

Notes reviewed either at special review or as part of OPD regular visit of patient
Audit against standards for reassessment and follow-up
Participation in on-going national audit
Surveys of user satisfaction

Look for:

1. *Home Therapy reviews documented in hospital notes*
2. *Clinic patients reviews weekly clinic meetings*
3. *Nurse adverse reaction audit*

F 2 Professional Development

Documentary evidence of satisfactory participation in continuing professional development for doctors and nurse
Evidence of participation in education activities relevant to the management of immunodeficient patients.
Nurses are members of the RCN Immunology and Allergy Group
Trust policy for monies to be available for CME for all staff
Nurses will be expected to be members of the RCN Immunology Special Interest Group

Look for:

1. *Consultant's Continuing Professional Development File*
2. *Nursing Profiles*

F 3 Appraisal of all staff

The Department has introduced an Appraisal policy.
Appraisals are taking place on an annual basis and in confidence.
Performance appraisal includes consultants

F 4 Patient involvement in management structure

Policy for involvement of patients
Minutes of regular meetings with patient representatives in keeping with clinical governance
Surveys of patient satisfaction discussed
There may be a regular Newsletters to patients

F 5 Quality Policy

A designated senior member of the Centre's management team should be responsible for quality issues
A written quality policy for the centre

Evidence that the Policy complies with the Trust's programme for corporate and clinical governance

F 6 All Centre protocols must be subject to regular document control

All Centre protocols shall be subject to regular review

With updating as appropriate

Superseded protocols be archived for long-term storage, in a manner that will prevent them being used inadvertently

Look for:

1. *Stored old protocols - marked appropriately*
2. *Dates and formats of protocols*
3. *Distribution lists and reminder that photocopying is not permitted*
4. *Protocols and policies for infusing Ig available (see also E4)*
5. *Policies and protocols for nurse prescribing (see also D7)*
6. *Risk of infection policy re blood sampling and infusions available*

F7 The Centre shall comply with all appropriate national and trust policies applicable to the provision of clinical care

Look for and enquire about use of:

1. *Manuals available -*
2. *Infection Control*
3. *Health & Safety*
4. *Trust Policies, Procedures and Guidance Folder*
5. *List of Staff with specific responsibilities:*
6. *Complaints co-ordinator:*
7. *Fire & First Aid Co-ordinator:*
8. *Back Care Co-ordinator:*
9. *IT Support Co-ordinator:*

F 8 Complaints

It is obligatory to have a Trust and departmental procedure for handling of complaints as part of clinical governance

Look for:

1. Documented policy for handling complaints.
2. Log of complaints
3. Trust Complaints policy

F 9 Research in PID

Minimum requirement to contribute to national UK register for determining prevalence of PID conditions

This includes home therapy and new forms of treatment (eg SCIg) to determine demand to ensure supplies

Evidence of participation in basic research in the field of primary immunodeficiencies is optional though desirable

Participation in clinical trials is variable though desirable

Look for:

1. List from consultants' CVs
2. Copies of reprints
3. Consent forms
4. Ethical approval letters
5. Clinical report forms for drug trials

Example of timetable for visit

The following meetings have been scheduled. Informal discussions will take place between assessors and other members of the Immunology team during ward visits, clinics etc.

Day 1		Venue
1030	Arrive – meet Trust contact	
From 1030	COFFEE	Meeting room.
1100-1700	Day-cases – with Clinical nurse specialist	Day-Care Unit
1130	Meet with CEO (or representative), Medical Director & Chief Nurse	Administrative offices
1215	meet with Senior Nurse, meet with relevant Pharmacist(s)	office Pharmacy,
1300-1400	LUNCH	Meeting room, level 4, West Link corridor
1400	Meet with Lead Clinician for Pathology	Pathology labs
1430	meet with related specialists eg Genetics, Respiratory physician, Gastroenterologist etc	Meeting Room,
1500	TEA	
1530	Clinical Scientist if relevant	office,
1600	Manager & clinical lead for service	office
Day 2		
0830-1330	Out-patients clinic – pre-clinic meeting followed by clinic	Out-Patients
11.30	write report in draft & consolidate data	
1300-1400	LUNCH	Meeting Room,
1400	Immunology trainee(s)	office
1500	Divisional Manager, Medical Services with Divisional Medical Lead, Medical Services	office
1600	FEEDBACK SESSION	Meeting room,

