Royal College of Physicians

Quality in Primary Immunodeficiency Services

QPIDS accreditation standards

December 2019

Summary

In September 2019, the QPIDS accreditation team launched a public consultation on the QPIDS standards. After a period of review, an updated set of standards has been produced.

What framework has been used to revise the standards?

The British Standards Institute (BSI) has developed a set of standards for accreditation of clinical services. The framework is known as PAS1616. The revised QPIDS standards are based on this framework, which covers leadership, risk, clinical effectiveness and patient and staff experience.

What are the key differences between the new standards and previous version of 2016?

The majority of the standards remain the same and some areas of evidence have been strengthened. There is more emphasis on supporting and developing the workforce, patient involvement and the overall governance and leadership of the service, which we know are important aspects of a high quality service.

When will the standards be re-reviewed?

Our standards are reviewed at least once every 5 years and so we expect the next iteration of the QPIDS standards to be in 2025. We recognise that guidelines and research may come out between now and then, which could impact the standards and so we may make some changes to reflect new practice. You will be notified by the QPIDS office team when this happens.

What is the transition plan for moving to the new standards?

If your service is already accredited, then you will be assessed against the new standards when your service is due for its 5-year assessment.

For registered services who are currently working towards the standards, there will be a period of transition and services will have until 31 August 2020 to **book** their accreditation assessment in order to be assessed on the existing standards. There is typically a 3-4 month lead in time from booking an assessment to the assessment taking place. If you think your service will be ready for an assessment in 2020, we strongly suggest you reserve an assessment by contacting the office team on 0203 075 1508 or askQpids@rcplondon.ac.uk.

All other services will be assessed on the new standards only, including any new services registering with the QPIDS programme.

Standard	Guidance	Evidence requirements
1. Leadership and management of the clinical service		

1.1 The service has an operational plan (quality manual) which is reviewed annually.	• This document should include as a minimum:
	  ○ organisational chart for the service
	  ○ vision for the service
	  ○ measurable objectives and key performance indicators for the service for that year
	  ○ plans for service development depending on local need
	  ○ plans for service improvement and innovation
	  ○ skillmix review including administrative support, appointments to support new or existing work, retirement planning and staff retention
	  ○ detailed pathways outlining how referrals are managed across different specialities and across other immunology centres (both to and from)
	  ○ key contacts for each companion speciality and evidence of joint working/clinical liaison (ENT, respiratory medicine, gastroenterology, infectious diseases, haematology/oncology, paediatrics, clinical genetics, rheumatology, dermatology) and other centres
	  ○ how the immunology service works with NHS England's specialist commissioning team and regional immunoglobulin advisory panels (IAPs) or equivalent.
	• The plan should be developed with multidisciplinary input.
		• Operational plan document.
		• Minutes of service management /clinical governance meetings where this is discussed.
		• Evidence of:
		  ○ working with specialist commissioning teams, where applicable
		  ○ working with regional immunoglobulin advisory panels or equivalent
		  ○ annual review of the operational plan
		  ○ joint working and co-operation with other clinical specialties (eg ENT, respiratory medicine, gastroenterology, infectious diseases, haematology/oncology, paediatrics, clinical genetics, rheumatology, dermatology).

Standard	Guidance	Evidence requirements
1.2 The service has a leadership team that is visible, approachable and communicate regularly with staff.	• The roles and responsibilities of individuals in the leadership team (medical and nursing) should be clearly defined (for example within an operational plan). • There are regular (at least quarterly) meetings to discuss service management issues. • Communication should include face to face methods (for example huddles/debriefs). • Communication to staff should include highlighting important changes to the delivery of the service, new statutory information impacting the service and updates on quality, safety and clinical governance. Communication about any changes to the delivery of the service may also be important to share with other teams (eg diagnostics, companion specialties, referrers, GPs etc).	• Document outlining roles and responsibilities of leadership team (note: this could be within the operational plan). • Minutes of regular management meetings. • Examples of communications to staff (eg notices/bulletins etc). • Evidence of dissemination of new statutory information (notice board/staff folders/minutes of meetings).
2. Person centred treatment and care		
2.1 The service has an up to date webpage which provides key information to patients.	The webpage must include the following as a minimum: • the scope of the service provided (including whether research or training is undertaken) • the range of services offered, frequency, their location(s), any satellite/spoke services, clinic times and how to contact services (email and phone numbers) • clinical staff members involved in delivering the service • facilities available, including access for users with specific needs • expected timescales for the patient pathway, including initial assessment, start of therapeutic interventions and the process for urgent reviews • any links with other clinical services/ stakeholders,	• Link to public-facing website. • Hard copy format provided to patients/carers who do not use the internet and means for providing this in other accessible formats, where requested.

Standard	Guidance	Evidence requirements
	including relationships with other organisations where referrals are sent/received and how the referral pathways are managed. • how patient involvement is incorporated into the running of the service. The external-facing information should be agreed in advance with patients/carers. The service must also state their expectations of patient which must include: • notifying the service of appointment changes or cancellations • discussing with the clinical team any desired changes to treatment/ care • visiting GP or other out of hours service as appropriate if unwell between appointments • discussing with the service where expectation of treatment/care are not being met • abiding by any codes of conduct (eg zero tolerance for aggressive behaviour) or patient/carer charters. The patient/carer should be encouraged to make contact with their immunology service if they are admitted to another hospital, to ensure specialist input is provided into their care.	
2.2 There are regular opportunities for patients/carers to provide feedback.	• Regular feedback is required and there should also be a PID-specific survey which should include: ○ views on the quality of treatment/care provided ○ involvement of the immunology team when patients are admitted under other teams or at a	• Patient/carer survey in the last 24 months. • Evidence of: ○ how patients/carers are continually encouraged to provide feedback outside of a formal patient survey (for example, posters in clinic, comment box etc)

Standard	Guidance	Evidence requirements
	different hospital ○ shared decision-making and involvement of the patient in their care ○ quality and clarity of information provided ○ access to psychological support ○ availability of patient information and education, and signposting to local/national support groups, particularly for paediatric-adult transition ○ dignity, respect and compassion ○ ease of getting in touch with the service and a response within 2 working days for non-urgent queries.	○ how the feedback is reviewed and acted on ○ how issues arising from feedback have been addressed and shared back with patients (for example, 'you said/we did' poster). ○ sharing patient/carer feedback to staff ○ other meaningful patient involvement in the service (eg patient days, attendance at meetings etc).
2.3 The service provides person-centred support based on individual needs.		○ Evidence of: ○ comprehensive written/online material available to support patient learning and evidence of providing this information to patients/carers (note: the material can be from patient groups) ○ signposting to local/national support groups (for example posters in clinical area ○ referral for psychological support, where indicated ○ communication to staff about their responsibilities for signposting and providing patient information ○ patient education to cover self-management.
2.4 The service has procedures for patient admissions.		• Procedure for patient admissions to include agreed pathway for admission from home, outpatients and daycase. • Evidence that the service ensures inpatient support/advice is provided to inpatient teams managing immunology patients in hospitals remote to the main immunology centre.

Standard	Guidance	Evidence requirements
2.5 The service supports patients transitioning from paediatric-adult and patients being transferred in/out from other regions.		• Document highlighting the process for transition from paediatric-adult (this could be within the operational plan). • Document explaining how transfers to/from other regions are managed. • Evidence of gathering feedback on the effectiveness of transition from different services and paediatric-adult transition.

2.6 The service monitors and reports on quality metrics and has an improvement plan supported by the management team.	• The metrics to monitor and meet fully are::
	  • waiting times for new outpatient appointment within national targets and capacity to see new urgent referrals within two weeks
	  • waiting time for follow up appointments should not exceed 2 months after the clinically agreed review date.
	  • 75% of clinic letters being sent to GPs and patients within two weeks of the appointment, including a facility for urgent letters to be sent within 2 days.
	In addition, the service must have a mechanism for recording delays in starting treatment for immunoglobulin and home therapy beyond the clinically agreed start date.
		• Report documenting each of the metrics.
		• Improvement plan for delays to treatment, where applicable.
		• Evidence of:
		  • meeting the targets for waiting times for new and follow up appointments as per guidance
		  • discussion at service management meetings and escalating through senior management where additional support is required.
		  • immunology staff being meaningfully involved in developing the improvement plan
		  • patient/carer involvement where applicable, to help support change and improvement.

2.7 The service undertakes a risk assessment of individual patients, where required.	• A risk assessment will be necessary when there is a risk of harm to the servicer user and/or others or challenging behaviour.	• Risk assessment template (could be organisation-wide). • Restraint and mental capacity procedure (or equivalent). • Where applicable, evidence of team discussion of patients who pose a risk and management plan (eg during handover, MDTs or equivalent). • Where applicable, evidence of liaison with safeguarding team for vulnerable adults/children.
2.8 The service ensures consent for clinical procedures.	• Written consent is required for patients treated with immunoglobulin and plasma derived C1 inhibitor products.	• Evidence of documentation in user records. • Clinical records audit to include consent (see standard 3.1). • Evidence of training/guidance for staff.

Standard	Guidance	Evidence requirements
	• In adult services, training /guidance is provided to staff for obtaining consent from patients with diminished mental capacity.	

2.9 The service records, investigates and learns from concerns and complaints.		• Evidence of:
		  • review of complaints and actions in service meetings. disseminating themes and actions to all staff in service.
		  • informing patients how to make a complaint.
		• Log of all complaints (formal and informal, including PALS) over the last 12 months including response times.

3. Clinical effectiveness		

3.1 The service participates in local and regional audit programmes.	• Audit evidence of clinical practice against protocols.
	• As a minimum, CVID and HAE should be each audited annually against local protocols/national consensus documents.
	• An annual audit demonstrating administration of immunoglobulin consistent with local protocols. Where immunoglobulin is administered in satellite/spoke departments services should provide audit evidence that immunoglobulin infusions are being administered in accordance with main hospital protocol in all satellite/spoke services and through home therapy.
	• An annual audit of at least 30 sets of randomly selected clinical records to include:
	  ○ PID hospital therapy patients.
	  ○ home therapy patients.
	  ○ HAE patients and
	  ○ outpatients.
		• Annual CVID, HAE, immunoglobulin administration, clinical records and coding validation audits.
		• Quality improvement plan developed as a result of the data generated from audit outcomes.
		• Evidence that changes made following previous audits have led to improvement.
		• Evidence of involvement in regional/network audit.

Standard	Guidance	Evidence requirements

	• The audit should include:
	  ○ date/signature for the last five entries.
	  ○ Evidence of discussion of treatment benefits and risks with patient (shared decision-making)
	  ○ evidence of consent to treatment (where appropriate)
	  ○ evidence of correspondence with GP from last two clinic appointments.
	• Coding validation audit, in collaboration with coding team.
	• Note: the audits should include the selection methodology for those patients/records being audited.	

3.2 The service participates in national audit/assessment programmes.		• Evidence of participating in QPIDS census. • Evidence of involvement in ESID/UKPIN registry and IVIG database.
3.3 The service reviews and updates all relevant guidelines, clinical pathways.		• Evidence of reviewing local or regional protocols for CVID, HAE, immunoglobulin use and all other conditions managed at the centre. • Evidence of reviewing guidelines and staff aware of how to access.
3.4 The service keeps a register of all research undertaken.	Register should as a minimum record at least the lead investigator from the centre and number of patients recruited.	• Register of research undertaken. • Evidence of communicating to team which research projects are ongoing.
4. Immunology workforce		
4.1 There is an appropriately trained consultant clinical immunologist in charge of the service.	• For adult services, a CCT (or equivalent) in immunology. • For paediatric services, a CCT (or equivalent) in paediatric infectious diseases & immunology. • For adult trained immunologists managing paediatric PID, evidence of joint clinics with paediatric immunologist or	• Evidence of inclusion on the specialist register, appraisal and revalidation. • Deputising arrangements, including holiday cover. • If single-handed, evidence of cases being discussed with immunology colleagues eg at network meetings or remotely.

Standard	Guidance	Evidence requirements
	MDT where specifics of paediatric patient management are discussed. • Single-handed practice is not recommended. If single-handed practice is unavoidable, evidence of working with other PID services to review cases, including attendance at immunodeficiency network meetings.	
4.2 There are appropriately trained senior nurses to provide nursing care and run the home treatment programmes.	• There should be a band 7 lead nurse with at least 1 years' experience of working in primary immunodeficiency and evidence of PID CPD. • For services with a deputy head nurse from another specialty, evidence of appropriate training and competencies. • For services seeing paediatric PID patients, job description/job plan of a paediatric trained nurse in the service.	• Job description/job plan for head nurse at band 7 or above, or equivalent. • Job description/job plan for deputy head nurse at band 6 or above, or equivalent. • Evidence of deputising/cover arrangements. • Evidence that satellite/spoke services are supported by appropriate trained nurses.
4.3 There is a service-specific induction process.		• Example(s) of methods for approaching induction for new starters. • Evidence of gathering feedback from staff about the induction process and what, if any, improvements were made.
4.4 The service carries out an annual appraisal for staff members.		• Staff log showing appraisal dates. • Evidence of 360°feedback (anonymised) for service leadership team (lead nurse and doctor) as a minimum.
4.5 The service has training plans and development opportunities in place for staff members and those contributing to the service.		• Mandatory training schedule and staff log showing compliance (100% compliance, with explanation of any non-compliance). • Evidence of: • support for staff to undertake CPD in quality improvement teaching and other developmental opportunities for learning (such as grand rounds, journal club etc).

Standard	Guidance	Evidence requirements
		• support for staff to attend national educational opportunities. • Examples of service-specific teaching/education, including for those outside of the immunology team (other specialties, primary care etc).
4.6 There are regular opportunities for staff feedback.	• Regular feedback is required and there should also be a immunology-specific annual survey which should include feedback on: ○ leadership communication and support ○ opportunities for training, development and making improvements ○ how staff are recognised and rewarded ○ the ability and process to raise concerns ○ support during incidents and near misses.	• Staff survey specific to immunology in the last 12 months. • Examples of how staff are encouraged to provide feedback. • Evidence of how issues arising from feedback have been addressed and shared back with staff.
4.7 The service has a process to assess staff members as competent in specialist techniques every two years and for new starters.		• Evidence of competency process for members of the team undertaking cannulation, venepuncture and administering infusions (as a minimum) and staff member competency logs. Note: this can be peer-assessed.
4.8. The service adequately supervises trainees and students.		• Evidence of trainees being adequately supported to fulfil their clinical duties.
4.9 The service encourages networking with other clinical services.		• Evidence of at least 1 department representative attending network meetings (at least 3 out of 4 meetings per annum) and evidence of sharing learning back with the team. • For UK services: As a minimum, lead nurse should be member of Immunology and Allergy Nurses Group UK.
4.10 The service supports employee wellbeing.		• Evidence of initiatives in place to support staff (eg process of referral to occupational health, support from managers, organisation-wide schemes such as Schwartz rounds etc).

Standard	Guidance	Evidence requirements
		• Example(s) of how individuals and teams are recognised and rewarded.
4.11 Staff members are informed of processes to raise concerns about any aspect of the service.	This should include: • raising general concerns • raising concerns about disrespectful or discriminatory behaviour • challenging questionable and/or poor clinical practice; • breaches of code of conduct and accountability; raising concerns of an ethical nature.	• Whistleblowing and raising concerns policy. • Evidence of communicating to staff how to raise concerns.
5. Risk and safety		
5.1 The service has a named individual responsible for managing risks within the service.		• Named individual responsible for risk management in the service and evidence of communicating their role to the team. • A copy of the risk management policy (could be organisation-wide). • Evidence of risk assessment and mitigation measures. • SOPs covering relevant common and specialist procedures (infusions and home therapy) and evidence of dissemination. • Risk register and evidence of discussion at management/clinical governance meetings. • Evidence of cascading information about risks to all team members.
5.2 There are procedures to safeguard patients and the health and safety of staff members.		• A safeguarding policy and evidence of its implementation.
5.3 There are procedures for reporting and investigating incidents, adverse events and near misses	This must include: ○ a statement encouraging staff members to report incidents, adverse events and near misses and how to report these	• A document (eg operational plan) that summarises safety/adverse event monitoring and reporting in the immunology service.

Standard	Guidance	Evidence requirements
	○ a process for notifying patients affected by adverse events and documenting in their records ○ a process for mitigating risk of incident(s) happening again.	• Summary of incident reports and investigations over the last 12 months and how learning has been applied. • Evidence of root cause analysis documents, where applicable. • Evidence of reviewing data from incidents in management/clinical governance meetings. • Examples of sharing key learning from incidents with staff, in mortality and morbidity meetings and with other networked departments, where applicable.
6. Systems to support service delivery		

6.1 Facilities and equipment are regularly assessed.	• This includes emergency equipment, including resuscitation trolleys.
	• Regular outpatient clinics for assessment and follow-up should be held separately for adults and for children.
	• If assessors are not able to visit satellite/spoke services due to distances and numbers, evidence of their suitability must be provided. This may include floor plans, photos and descriptions, and patient feedback.
		• Evidence of:
		  • robust systems for dispensing and storage of immunoglobulin products
		  • completing regular environment checklists (eg patient-led assessment of the care environment or equivalent)
		  • annual review of facilities/equipment and replacement schedule (eg business cases).
		  • this standard being met in satellite/spoke services.
		  • nursing and medical staff having access to administrative support and adequate office space (including access to necessary hospital systems, telephones, computers, email and internet).
		• Pathways for children being seen by the service and evidence that this is in a separate area or time to adults being seen.

Standard	Guidance	Evidence requirements
6.2 There is appropriate support from laboratory and radiology services.		• Evidence of laboratory services UKAS accreditation or equivalent. • Evidence of timely access to radiology.
6.3 The service has a process for document review and control.	A system of document control management, to include: • dates and formats of protocols • version numbers • planned review dates • author and authorising individual • who the distribution list is and that a reminder that photocopying is not permitted.	• Evidence of protocols and local patient information meeting this standard. • Evidence that document management is included in staff induction.
7. Home therapy		
7.1 The service has appropriate facilities and equipment available for undertaking home therapy training.	• Sufficient pumps for caseload (determined locally). • Local arrangement or contracts for immunoglobulin and sundries. • Environment for training should consider privacy and dignity.	• Evidence of audit of any delays as per standard 2.6 Note: The equipment and facilities will be assessed during the on-site assessment.
7.2 There is a home therapy caseload sufficient to maintain nursing competency and expertise, and appropriate numbers of trained and experienced staff to provide adequate home therapy training and support.		• Data regarding number of patients trained in the last year and number of competency assessment reviews undertaken. • Evidence of staff training and competency. • If home visit are undertaken, lone worker policy/safety of staff going on visits.

Standard	Guidance	Evidence requirements
7.3 The home therapy training programme is organised with nationally agreed guidelines.		• Local policy demonstrating alignment with European guidelines.
7.4 There is documentation which indicates the consent of the patient for home treatment (and/or infusion partner, if applicable).		• Information supplied to patients prior to commencing treatment. Criteria for inclusion in home therapy program. • Consent completion with documentation filed in case notes. • Evidence of interaction with primary care prior to institution of therapy and during ongoing care.
7.5 Patients and partners are given necessary training,including written information and supporting materials.		• Documentation of training as per guidelines. This includes a paediatric trained nurse to train parent carer for paediatric patients. • Examples of assessment protocol/paperwork exercise completed at the end of the training programme. • Examples of approach to completion/sign-off at each stage of training.
7.6 Competency assessments are carried out for patients/carers.		• Evidence that the need for competency assessments is discussed with all home therapy patients. • Evidence of ensuring new home therapy patients are reassessed within two years and when equipment/procedures are changed. • Evidence that home therapy technique is maintained through practical reassessments of patient/carer competencies.* • Regular submission of logs (and diaries, if used). Note: The timeframe can be determined locally. National consensus guidelines regarding frequency of reassessments are expected in Spring 2020 and this standard will be updated in due course.

Standard	Guidance	Evidence requirements
7.7 The service has an up to date database of home therapy patients.		• Standalone or integrated register of home therapy patients (local/national/international). • Participation in IVIg and SCIg home therapy registers (if present).
7.8 There is a survey of home therapy patients every 24 months.	There is, as a minimum, a formal survey of all home therapy patients every 24 months. The feedback should cover patient/carer experience of the local training programme and privacy and dignity for home therapy.	• Survey at least once every 24 months and results • Evidence that surveys are distributed to all home therapy patients. • Evidence of discussion of feedback and plans to continue to improve.