

16(a) Specialised immunology services (adults)

1. Recommendation of what the NHS Commissioning Board will commission

The NHS Commissioning Board will commission specialised immunology services for patients with deficient immune systems (including complex autoimmune and vasculitic conditions complicating deficient immune systems) from specialised immunology hub centres.

2. Four TOG questions

TOG question	Response
Which elements of the service will be commissioned by the NHS Commissioning Board?	<p>The NHS Commissioning Board will commission a service for patients with:</p> <ul style="list-style-type: none"> • Deficient immune systems; all primary immunodeficiencies • Subsets of autoimmune and auto inflammatory disease where they are associated with immunodeficiency syndromes • Complex autoimmune and vasculitic conditions in a shared care role with other specialist centres <p>The NHS Commissioning Board will commission services for patients that require cytokine and other immunomodulatory therapies for the above conditions</p> <p>Hub and spoke arrangements exist for immunoglobulin and C1nh replacement under the supervision of the specialist centre. The centres should support outpatient/home self-care for immunoglobulins for the majority of PID patients.</p>
Which elements of the service will be commissioned by CCGs?	CCGs will not commission specialist adult immunology services for immunodeficiency (but may commission local immunology diagnostic laboratory support or clinical services, and local allergy services outside of the specialist services definitions)
How will activity be separately identified?	There are sufficient ICD10 codes to define most of the PID specialist activity but they will not be recorded for most OP consultations at present. However it is possible to identify the PID activity easily on a named patient basis as each centre will have a sufficiently low numbers of patients and all should have a database as part of

	<p>accreditation requirements.</p> <p>There is considerable room for improvement in the granularity of coding, especially for complement deficiencies, including C1inh deficiency but it is not essential for defining the specialist activity at present. IUIS definitions of PID could be used if needed.</p> <p>OPCS codes are insufficiently detailed to specifically describe activities such as immunoglobulin replacement or C1 inhibitor infusion but this activity can be monitored by local coding of activity, the demand management database recording immunoglobulin usage and the local patient database.</p> <p>Patient self-administration of immunoglobulin activity data may be difficult to capture at with existing data capture systems, but could be counted through local databases and pharmacy records, existing home therapy delivery company contracts or via a simple common web-based database system.</p> <p>The immunoglobulin demand management programme database can currently track intravenous and subcutaneous immunoglobulin usage and number of antibody deficient patients per centre. The national UKPIN database or the DMP database could supplement this function for in the longer term as part of accreditation and quality dashboard requirements.</p> <p>Appropriate reimbursement of specialist centres for provision of home therapy programmes is difficult without national commissioning - current tariff/funding structures reward hospital-based treatment over home treatment.</p> <p>There is no current methodology which can capture the element of regional/sub regional specialist advice and support given to other services on clinical and laboratory diagnostic immunology from that provided locally e.g. in multidisciplinary care for complex autoimmune disease.</p>
How many provider contracts will there be?	<p>28 provider contracts</p> <p>Contractual arrangements for outreach clinics in more local hospitals will be made through the specialist centres.</p>

Running costs associated with commissioning the service	<p>It would be more efficient to commission the service nationally so that planning can be optimised. This would also allow the introduction of common commissioning policies.</p> <p>Costs would likely be reduced if the service was commissioned in totality by the NHS Commissioning Board rather than by many, smaller organisations.</p>
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3. Four factors on the bill

Factor	Still met?
The number of individuals requiring the service	Yes – there are about 4,000 primary immune deficient patients in England (and approximately 5000 in the UK)
The cost of delivering the service	There is a significant staffing infrastructure required to deliver the service and some of the drugs/therapies used can be expensive.
The expertise required to deliver the services	A small number of expert people deliver the service.
The financial risk to CCGs	Small numbers of patients and expensive treatments with considerable potential variation (complex patients can be very expensive)

4. Assurance processes

Assurance Group	Comments
Clinical Assurance Group	<ul style="list-style-type: none"> The PID element of the scope is clear but the other two areas do not sufficiently define and differentiate specialised and non-specialised activity This has been clarified – 95% of the Specialist immunology activity will relate to deficient immune systems and immunologist involvement in care of vasculitis/autoimmunity is predominantly in a shared care role and predominantly supports other services as NSSDS, including Definition No.11, Specialised Renal Services (adult) Definition No.26 Specialised Rheumatology Services (all ages) No.24, Specialised Dermatology Services (all ages) Definition No.29, Specialised Respiratory Services (adult)
Patient and Public Engagement Group	<ul style="list-style-type: none"> Patient representation to be confirmed

	<ul style="list-style-type: none"> • The summary of the scope should define what is meant by a 'network' in the context of that particular scope as this can be defined in a number of ways • Clarification added. There is no strategic clinical network. UKPIN is a formal, national, professional, unfunded network which provides a peer-accreditation process. It is not a managed network but could act as an important resource for a formal managed network if desired. The optimal harmonisation and governance configuration is to adopt the UKPIN National Professional Network as the primary accreditation body for specialist services and this could be the engine for harmonisation of patient pathways and clinical practice if appropriately resourced. If PID is not to have a strategic network, it could underpin a managed network or simply provide a key component of the quality dashboard and harmonisation process. Accreditation should be mandatory for specialist practice. Participation in Regional and local professional networks such as TRIAC who are providing professionally led audit and guideline harmonisation should be encouraged.
SCG Finance Network	<ul style="list-style-type: none"> • Activity would need to be identified through a named patient list. This is understood to be feasible for PID patients (given many of them are on drugs); recommended that this is the approach for other immunology patients – is this feasible? • Yes – in fact with further consideration we are confident we have a workable model for counting activity now by triangulation of pharmacy, OP CRG coding and local patient databases for PID, and the potential for better monitoring in the future (see scope).
Finance Assurance Group	<ul style="list-style-type: none"> • Issue of whether patient can be identified through a register needs to be resolved before assurance can be given

5. Other key issues that the CAG needs to note:

- A few centres may be unable to reach accreditation or quality standards and may have to cease providing specialised services.
 - This is acknowledged, the options for a centre who does not achieve quality standards are to improve or to cease providing the service.
- Introducing the scope would mean a national approach to the funding of C1inh and cytokines, many of which are currently funded through IFRs.

- True, but there are many potential advantages for commissioners and patients from this approach
- There are considerable overlaps with specialised allergy services.
 - True of some, but not all centres. The centres and staff may be multifunctional, however the PID activity and resource needed to support that part of the service can now be separately identified using the methodology proposed. All specialist centres will have some non-specialised activity commissioned locally, however in the case of rare PID diseases; all activity will be nationally commissioned as specialist.

SSDS 16 Immunology

Final Scoping Document v2.0. 30th April 2012

1. The Need for Specialist Immunology Services

There are over 150 different but rare immune deficiencies recognized by the European Society for Immunodeficiencies (www.esid.org).

These diseases individually range in prevalence from 1 in 3,000 to less than one in a million.

In total there will be approximately 4,000 Primary immune deficient (PID) patients in England (adults and children combined) including C1inh deficiency. Currently 1,210 UK PID patients are listed on the ESID registry database (although incomplete at present it is an obligation on all centres applying for accreditation to keep a local patient database and submit to the national database) and the immunoglobulin demand management database reports 2078 patients on long-term intravenous and subcutaneous immunoglobulin replacement for antibody deficiency as of March 2012. This number may rise as re-imburement will depend on database submission from April 2012 and we determine if the capture of data from home delivery companies is complete.

There are 600-900 patients with Hereditary Angioedema (HAE), 500 patients under investigation or observation but not yet on immunoglobulin at any time, and 500 with other primary immunodeficiencies not requiring immunoglobulin replacement in the UK as a whole. There may also be up to 1000 additional patients on immunoglobulin by home delivery which are not yet captured as of March 2012 but will be in future. Thus there are approximately 4000 cases in England at any one time (adults and children). Mandatory accreditation and database requirements would make counting of the number of PID patients relatively easy to implement locally and the national database is one potential central web-based portal for identifying patients for contract monitoring. OPCS and activity coding for OP activity will allow costing on an out-patient based PBR basis or a year-of care tariff.

The rarity, spectrum, potential severity of their morbidity and mortality and complexity of treatments require that PID be managed by immunology specialists (UKPIN Consensus, ESID).

Delayed diagnosis remains a concern for physicians and patients and continues to be an issue (PIA consensus documents and patient evidence from Hereditary Angioedema (HAE) UK and the Chronic Granulomatous Disease Society (CGD Society). Specific Primary Immunodeficiency and professional PIA advice on commissioning has been produced, as has an integrated care pathway incorporating patient stories.

Given the immunological mechanisms underlying the diagnosis and treatment of allergic disease, some specialist immunology centres are also major providers of specialist services for complex allergy encompassing the definitions in SSDS No 17 (El-Shanawany et al. J Clin Path 2005;58:1283-90). Likewise some allergy centres will care for HAE patients even though it is classified as a primary immunodeficiency. Therefore some immunology or allergy centres will provide services under both NNSDS 16 and NSSDS 17 utilizing the same medical, nursing, support staff and facilities.

Separation of activity for costing purposes is relatively straightforward but will need to be done on a local basis initially, since TRF coding is collected for activity and OCD codes can be linked to the 100-300 patients in each centre identified through local patient databases.

Longer term solutions, populated by the services, utilizing national PID, national allergy or national web-based specialist commissioning databases should be achievable.

Paediatric Immunology and Infectious Diseases are closely linked and their training programmes overlap. Up to 50% of the “Paediatric Immunologist” workload may be related to infectious disease in some centres. They will therefore also be defining their combined services scope under the Paediatric Medicine CRG. However activity separation can be achieved as above.

Specialist Immunology Services

Primary Immunodeficiencies

Immunology PID services primarily involve the diagnosis and management of deficient immune systems, mostly inherited (mainly included within ICD-10 codes D70, D71, D76, D80-89 (latter group – Certain Disorders involving the Immune Mechanisms)).

These diseases are all rare and are listed in the IUIS classification 2011 (<http://www.iuisonline.org/iuis/index.php/primary-immunodeficiency-expert-committee.html>)

All involve:

Multidisciplinary teams: Consisting of Specialist Doctors, Specialist Nurses, Dieticians, Physiotherapy and Social work support.

Home Care Programmes: Half of immunoglobulin replacement is delivered through managed home care programmes involving a multidisciplinary team.

Services for children and specialised transition arrangements

Adult and Paediatric services are usually separate but work closely together and are often co-located. Transition arrangements for seamless transfer of care between adult and paediatric services should be in place in specialist centres.

Care of rare autoinflammatory disorders which are associated with immunodeficiency syndromes as defined by European Guidelines associated with disordered immunity (these patients are a subset of the PID above):

Use of high cost-low volume drugs including biological agents in complex cases, often through individual funding requests

A few centres undertake shared care of complex autoimmunity for small numbers of patients: Specialist immunological management of complex autoimmune and vasculitic conditions, including diagnosis and treatment is often undertaken in collaboration with rheumatology, respiratory and neurology services in small subsets of patients (these services will be also covered by rheumatology services predominantly NSSDS 26)

Immunoglobulin Demand Management

Specialist immunology centres have a key role in implementing the Demand Management programme (DMP) (<http://www.ivig.nhs.uk/>). Immunologists often lead the process as chair of local immunoglobulin panels.

Replacement immunoglobulin therapy and immunoglobulin therapy for autoimmunity (for chronic inflammatory demyelinating neuropathy and other conditions) is delivered and monitored through hospital based and home therapy services (<http://www.nursingtimes.net/nursing-practice-clinical-research/training-and-support-to-enable-home-immunoglobulin-therapy/205157.article>)

Home delivered immunoglobulin is equally as expensive as hospital administered immunoglobulin and potentially subject to similar shortage in supply. All activity needs to be captured and governed in a similar way. Specialist immunology centres will be central to this.

2. The Nature of the Service

There are approximately 26 adult PID centres in England.

All clinical immunology activity dealing with primary Immunodeficiency (PID NSSDS 16) is specialist, in the same way that specialist management of Cystic Fibrosis is specialised. The service deals with rare and/or complex immunodeficiency primarily but the total number of patients is low overall, and will eventually be fully captured by National and European Databases (www.esid.org/research-database).

Patients present at any stage, from immediately after birth to over 70 years of age depending on the condition. There are sufficient differences in adult and paediatric care pathways as well as the types and presentations seen at different ages that the services may need to be separate, but work collaboratively.

Immunology services also act as a gateway for selecting that rare subset of immunodeficient patients who may benefit from the use of cytokine and other immunomodulatory therapies which may require development of commissioning policies to minimise the use of individual funding requests.

They are the primary gateway to use of immunomodulatory therapies and immunoglobulin replacement therapy in these conditions. Immunologists have a lead role in immunoglobulin demand management structures (<http://www.ivig.nhs.uk/>)

Most have an active role in audit and research into Primary Immune deficiencies as defined in UKPIN standards (<http://www.ukpin.org.uk/home/standards.htm>)

The current geographical distribution of existing services facilitates equity of access to services, with some room for improvement, although there are some regions where patients are obliged to travel long distances for expert care.

Most Immunology centres look after PID patients as their main specialist workload. A few immunology centres also have immune-rheumatology practices for subsets of rheumatological disease such as vasculitis or systemic autoimmune diseases such as lupus (<http://www.rcplondon.ac.uk/resources/publications/consultant-physicians-working-patients>).

Specialist immunological advice on use, complications and monitoring of biological and immunomodulatory therapies in other specialties including rheumatology is an additional component of specialist service delivery. Recognising this activity through coding will be a challenge, as the primary specialty against which it is recorded may vary.

All of the above activity is specialist in nature and delivered currently on a regional and sub-regional basis.

All centres will have a need for multidisciplinary team (MDT) working due to the complex nature of the conditions and heterogeneity of patient presentations including Specialist Nurses, dieticians, physiotherapists, genetic counselors and social workers. Often these teams provide an allergy specialist service as well.

Hub and spoke and outreach specialist services are often delivered, together with education and support for shared care for networks and peripheral hospitals. Immunology Nurse Specialists are essential to operate home therapy provision safely for patients.

Access to a specialist diagnostic immunology laboratory is an integral component of the service but generally funded separately.

Most immunology referrals are from other secondary care physicians. Direct referral from primary care is unusual. Many immunodeficiency disorders are picked up through specialist diagnostic immunology laboratory provision where antibody deficiency is noted.

Thus the main issues for this specialist service are the mechanisms of funding and the risks to future service provision in the new commissioning environment, not the referral source.

3. Review of ICD-10 and OPCS Codes

Differentiation of local activity from specialist activity should not be a major issue for primary immunodeficiency, since provision of a “local” service and regional/sub regional service for PID is the same specialist activity.

Most immunology hospital activity takes place in an outpatient (OP) or day case setting or through management in hub and spoke/ outreach clinic arrangements with other hospitals. HES data may be of limited use.

There are sufficient ICD10 codes to define most of the PID specialist activity but they will not be recorded for most OP consultations at present. However it is possible to identify the PID activity easily on a named patient basis as each centre will have a sufficiently low number of patients and all should have a database as part of accreditation requirements. There is considerable room for improvement in the granularity of coding, especially for complement deficiencies, including C1inh deficiency but it is not essential for defining the specialist activity at present. IUIS definitions of PID could be used if needed. OPCS codes are insufficiently detailed to specifically describe activities such as immunoglobulin replacement or C1inhibitor infusion but this activity can be monitored by local coding of activity, the demand management database recording immunoglobulin usage and the local patient database.

Increasingly, patient self-administration of immunoglobulin in immune deficiency and autoimmunity (and or antibiotic treatment) at home through hospital-managed home therapy programmes is delivered through immunology centres. This activity data may be difficult to capture at with existing data capture systems, but could be counted through local databases and pharmacy records, existing home therapy delivery company contracts or via a simple common web-based database system. The immunoglobulin demand management programme database can currently track intravenous and subcutaneous immunoglobulin usage and number of antibody deficient patients per centre. The national UKPIN database or the DMP database could supplement this function in the longer term as part of accreditation and quality dashboard requirements.

Appropriate reimbursement of specialist centres for provision of home therapy programmes is difficult without national commissioning - current tariff/funding structures reward hospital-based treatment over home treatment.

There is no current methodology which can capture the element of regional/sub regional specialist advice and support given to other services on clinical and laboratory diagnostic immunology from that provided locally e.g. in multidisciplinary care for complex autoimmune disease.

4. Quality and Networks

All PID are complex and require specialist knowledge, training and expertise for optimal diagnosis and management. Services are delivered exclusively by adult or paediatric physicians and specialist nurses trained in Immunology.

Continual CPD and networking to keep abreast of new developments in diagnostics and therapy is required as there are regular developments in the specialty.

Many services work in networks, mostly informal and unfunded. Examples include:

(<http://www.nlg.nhs.uk/services/TRIAC/>) informal, regional, professional, unfunded – no commissioner involvement – involving nurses, doctors, dieticians, trainees and scientists

(<http://www.nwscq.nhs.uk/A2Z/i.html#clinimm>), formal, regional, part-funded, commissioner involvement. Multidisciplinary.

(<http://www.ukpin.org.uk/home/>) formal, national, professional, unfunded. Multidisciplinary and peer-review accreditation standards and process.

Informal professional or educational networks have been developed in paediatric and adult immunology between centres to optimize expertise in the management of these rare conditions both in the north and south of England. These maintain the critical mass of expertise and shared experience. Many paediatric conditions (and increasingly some “adult” ones) can be treated by bone marrow transplantation/gene therapy. Diagnostic immunology laboratory testing is usually provided from the adult service to support adult and paediatric care provision

Shared protocols and guidelines have already been developed in some multi-centre regional groups (<http://www.ukpin.org.uk/home/> and professional networks (<http://www.ukpin.org.uk/home/standards.htm>) to harmonise care and could be used to underpin policy development with patient group involvement.

A peer-review accreditation process with professionally agreed Service standards and an inspection process have been developed through the UKPIN professional network to harmonise care. <http://www.ukpin.org.uk/home/accreditation-standards.html>. Currently there are 5 fully accredited centres in England with the others registering or preparing for accreditation. This process should be mandatory for Specialist centres.

Hub and spoke arrangements for immunoglobulin and C1inh replacement and/or local clinics under the supervision of the Specialist centre, but may be counted and funded at the DGH and require to be mapped to the specialist service to reduce variation in service provision and cost.

5. Workload

5.1 In-patient activity

Most patients require multidisciplinary care, often shared with other organ-based medical specialties. The majority of PID patients have outpatient/home self-care based for immunoglobulin, but access to home treatment for C1inh deficiency is patchy. In-patient stays will be recorded under other members of the multi-disciplinary team (respiratory medicine/infectious diseases). HES data is thus incomplete and not a good indicator. Depth and accuracy of current coding is inadequate and unreliable. However activity related to named patients on local patient databases could be captured locally.

5.2 Outpatient workload

5.2.1 Adult Immunology

TRF codes can be used but additional measures will be needed as above to differentiate PID specialist activity from other local or allergy activity as follows:

It should be possible to differentiate immunology OP workload on basis of the locally identified PID patient cohort. All centres will know who they are. All Immunology activity will be specialised under this definition.

Immunology Centres generally use immunology TRF codes 313 (Clinical Immunology and Allergy) and 316 (Immunology) for recording immunology outpatient activity. Code 313 may currently also be used to code allergy activity in immunology centres. Moves are in place to rationalize coding to single TRF code for immunology activity and one for allergy which will simplify differentiation. Only a minority of immunology centres currently exclusively utilise Allergy code 317 for allergy activity, but this will be solved for the allergy component of activity with rationalisation of the codes and the same mechanism as proposed in the allergy scope can be used to differentiate the specialist component of the allergy activity in an immunology centre.

Procedure codes (OPCS) and HRG codes are currently insufficient to describe the standard procedures that may take place in an immunology clinic or day case episode (e.g. immunoglobulin replacement therapy or C1inhibitor replacement). However pharmacy records and local patient databases can be used to count activity accurately locally and will also be able to identify and account for all use of high cost drugs through the service.

Year of care tariffs are one possible way to simplify accounting. Complexity and cost of the individual patient's care will differ markedly. Some patients will be very complex and costly. This is not captured easily with current systems. A proposed Year of care tariff with banded levels of complexity is in early development and may address this problem.

Hospital to hospital referrals could be counted as another indicator of referral workload. Intra-Trust referrals will be more difficult to count but would be common where a provider has multiple specialist services. However we are confident on reflection that the above proposals are sufficient to capture the workload and that there is little need for this in identifying immunodeficiency activity.

A separate web-based database could be used to monitor specialist activity nationally, fed by local data, populated by local management and clinical teams. A similar process works well for Cystic Fibrosis Services.

5.2.2 Day Case Activity

Immunoglobulin replacement, cytokine and biological therapy will be administered in a day care environment. Day case OPCS and HRG coding is insufficient to accurately record this activity and many centres use existing OP codes plus OPCS codes, or have locally agreed tariffs leading to variation in costs across centres. National Commissioning and dashboards offers an opportunity to address this variation and harmonise this.

Specific additional granularity in OPCS and TRF codes are required for precise activity data collection through existing systems, but the proposals above are workable and should achieve the same end without the need for additional codes.

5.2.3 Home Therapy Services

Home therapy Hub and spoke and outreach specialist services are often delivered, together with education and support for shared care for networks and peripheral hospitals. Funding arrangements are complex and variable. Standardisation due to national commissioning would benefit patients and the NHS.

Current commissioning arrangements for home therapy services are complex and tend to reward hospital based care. Immunology specialist nurses are essential to operate home therapy provision safely for patients. Standardisation due to national commissioning would benefit patients and the NHS.

6. Transitional Care

Guidelines for best practice have been developed and should be a key component of an adult and paediatric specialist service.

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083592).

7. Entry Criteria

Most immunology referrals are from other secondary care physicians and paediatricians. Some immunodeficiency disorders are also picked up through specialist diagnostic immunology laboratory provision. Direct referral of patients with confirmed PID from primary care is unusual. Because specialist services cluster in the same providers, a considerable number of referrals will be from within the same hospital service.

8. Exit Criteria

A patient with primary immunodeficiency will require life-long care. Patients referred for diagnosis who are not found to have a primary immunodeficiency will be discharged back to primary care or the care of the referring hospital.

9. Assessment

9.1 Diagnosis

Specialist immunology services utilise specialist diagnostics to establish the diagnoses including triaging for specialist genetics. Many centres will provide specialist diagnostic assays for use in these cases – for example flow cytometric evaluation of memory cell subsets, specific functional assays of the immune system etc. The centre also provides support for other specialties requiring specialised immunological testing.

Immunology centres liaise closely with the specialist BMT services to enable early transfer to appropriate centres for a subset of patients and subsequent local monitoring and specialist care after transplantation.

9.2 Home Therapy

Selection of patients for home therapy and support, training and management of home administered immunoglobulin and C1inh therapy is a key role of the specialist centre which facilitates integrated care (see above)

10. Funding/Commissioning

Immunology OP activity is currently a Tariff exclusion.

Specialist Immunology Services are usually subject to local commissioning arrangements and funding mechanisms are diverse. Some have been identified and supported by LSCAGs in the past but most are now funded through the PBR mechanism or local arrangements. There is a clear risk to the services in the new commissioning environment if local CCGs determine that provision of regional services are not a priority, or complex negotiations are required with multiple commissioners to secure funding.

National commissioning would ensure excellence, equity of access and continuity of provision, improved quality and be consistent with national consultations on rare diseases (<http://www.dh.gov.uk/health/2012/02/consultation-rare-diseases/>) and patient choice.

Costs should not increase as a result, but variation, quality and cost-efficacy should improve under national commissioning arrangements.

Local arrangements are diverse. There is frequently a need for use of high cost-low volume drugs by individual funding requests (IFR) request such as C1inh (enzyme) and interferon gamma (cytokines) for complex patients. Access to these drugs is currently delivered inconsistently across the country. A recent survey of 50 CCGs by HAE UK revealed that there were only 5 with commissioning policies for C1inhibitor replacement with no consistency in content or approach.

11. Conclusion

In terms of the four factors set out by the Secretary of State:

1. The number of individuals who require the provision of the service or facility
 - a. This meets the criteria for specialist commissioning.
2. The cost of providing the service or facility
 - a. This is unlikely to be higher than at present. There is room for improved cost-efficacy and quality improvement with reduced variation
 - b. There appear to be no requirements for equipment and facilities which do not already exist.
 - c. There is a clear rationale for maintaining and expanding the existing network functions to harmonise provision and improve cost effectiveness. A formal network could be envisaged to harmonise quality, care and common dashboards. Examples of some of these networks and accreditation processes already exist.
 - d. The risk to patients and existing services is high if national commissioning is not undertaken.
3. The number of persons able to provide the service or facility
 - a. This is currently small but sustainable with current trainee numbers (CfWi reports). Even if consultant workforce increased to the recommended level in "Consultant physicians working with patients" it would not exceed the specialist service definition limits.
4. The financial implications for CCGs if they were required to arrange for the provision of the service or facility.
 - a. The infrastructure already exists.

- b. Service costs are already born locally and therefore the main challenge is to identify current activity, given that current methodologies are insufficient to capture it accurately now. There are proposed, robust and achievable measures that could be undertaken to estimate current workload and derive appropriate costings in parallel with tariff review and new mechanisms are proposed above.
- c. The financial risks to individual CCGs of large variations of cost due to significant variation in numbers or complexity of rare diseases or use of high cost-low volume drugs (biologics and cytokines) in year would be reduced by national commissioning.
- d. There should therefore be no major financial risk to commissioners overall and little likelihood of uncontrolled expansion of demand.
- e. Common commissioning policies will reduce variation in care and potentially reduce costs through harmonisation.

APPENDIX B GROUP 3 SERVICES – TEMPLATE FOR SERVICE SCOPE DEVELOPMENT

This template is intended to provide a checklist to aid the development of service scopes and also to provide an audit trail to demonstrate that all the principles for service scope development have been factored into the discussions.

Name of service:

SSPS16 Immunology

1. Does the scope reflect version 3 of the Specialised Services National Definitions set?

Yes.

2. Does the scope reflect existing service specifications and policies, where they exist? Please list any considered.

There is no policy or service specification for commissioning Immunology services at present.

An Immunoglobulin Demand Management policy mandated by the Department of Health is in place and monitors subcutaneous and intravenous immunoglobulin use.

Immunoglobulin demand management is critically dependent on immunology services (usually led nationally)

HAE -UK recently surveyed 50 CCGs and only identified 5 local policies for use of C1 inhibitor therapy, all different. A common national policy is required, perhaps analogous to the immunoglobulin demand management programme.

3. Does the scope reflect any agreed professional standards, both those listed in the SSNDS and those developed since their publication? If the service is a paediatric service, does it reflect the clinical relationships set out in *Commissioning safe and sustainable specialised paediatric services: a framework of critical inter-dependencies*? Please list those developed since publication.

Yes the scope reflects the professionally agreed accreditation standards developed by the UK PIN accreditation process (<http://www.ukpin.org.uk/> see below).

Additional standards and guidance developed since publication of NSSDS V3:

1. Primary Immunodeficiency Association Commissioning document

Executive Summary

By Matthew Helbert, Consultant Immunologist; Manchester Royal Infirmary

Introduction
 The primary immunodeficiencies are a group of rare diseases that remain poorly recognised and treated by non-specialist healthcare professionals. While severe combined immunodeficiencies and related disorders have received funding through national specialist commissioning arrangements, services for other primary immunodeficiencies have developed largely due to individual effort, often expanding in a relatively unstructured and inadequately resourced way. The central message of this publication – that adults and children suffering from these disorders should receive specialist care from health professionals appropriately trained in their management – is clearly set out and is fully endorsed by UK Primary Immunodeficiency Network (UKPIN).

This document is consistent with, broadens and explains the information provided in the National Specialised Definitions Set (Specialised Immunology, number 16). *Dr. Phil Wood - Chair, UKPIN*

What are primary immunodeficiencies?
 The immune system is the body's defence against infection. Any defect in this defence system will predispose affected individuals to recurrent, severe infection leading to disability or death.
 In the primary immunodeficiencies (PIDs), the problem arises from defects within the immune system itself, sometimes because of inherited gene mutations. Patients with PIDs will develop serious infections throughout life unless adequately diagnosed and treated.

PRIMARY IMMUNODEFICIENCIES	SECONDARY IMMUNODEFICIENCIES
SCID	HIV
XLA	Cancer
CVID	Chemotherapy
Antibody deficiency	-

Rhys Evans (centre) was born with X-SCID and no resistance to infection. X-SCID is one of the most severe primary immunodeficiencies.

“Commissioning arrangements need to ensure PID patients receive specialist care and that they have access to appropriate treatment delivered via home therapy or hospital clinic.”

There are over 80 conditions⁽¹⁾ that have been identified as PIDs. These often present in the form of ‘ordinary’ infections, which are treated by physicians who often miss the underlying cause. This allows the illnesses to recur and leaves the patient vulnerable to vital organ damage, physical disability, and even death⁽²⁾. Research has estimated that average diagnostic delays range from 2 to 5 years for the commonest forms of PID, the Primary Antibody Deficiencies⁽³⁾⁽⁴⁾. The life expectancy of patients is significantly reduced, largely because of respiratory failure and malignancies.

Included in this group are individuals with Hereditary Angioedema (HAE), or C1 inhibitor deficiency, a condition in which potentially life-threatening attacks of tissue swelling (angioedema) can occur in an unpredictable manner. These patients are often managed by immunologists within PID centres.

2. Consensus Document on C1 inhibitor (Gompels, MM and Lock, RJ and Abinun, M and Bethune, CA and Davies, G and Grattan, C and Fay, AC and Longhurst, HJ and Morrison, L and

Price, A and Price, M and Watters, D (2005) C1 inhibitor deficiency: consensus document. **Clinical and Experimental Immunology** , 139 (3) 379 – 394)

3. Integrated Care Pathway for C1 inhibitor (in preparation)
4. Consensus document on Antibody Deficiency Deficiency 1995 and updated 2011 <http://www.rcpath.org/publications-media/publications/consensus-document-for-the-diagnosis-and-management-of-patients-with-primary-antibody-deficiencies>
5. UK PIN standards for diagnosis and management of PID and position statement <http://www.ukpin.org.uk/home/standards-position-statement.htm> and <http://www.ukpin.org.uk/home/standards.htm>

4. Does the scope reflect national policy direction, where this exists? Please list the names of policy/ies reflected.

The list of polices reflected are:

1. Long term conditions
2. Rare diseases
3. Networks
4. Immunoglobulin demand management plan
5. Choice
6. Equity and Excellence

5. Does the scope result in fewer than 50 providers (if the service is for all ages) and fewer than 20 providers for children's services? If not, explain the reason for this. Please append a list of the providers that would deliver the service?

Yes there are 26 centres in England. For details please check the BSI Clinic list "find an immunologist" <http://www.immunology.org/page.aspx?pid=1349>

PID services may receive referrals from outside England and this needs to be taken into account.

Providers delivering the service would be:

1. Mostly teaching hospitals
2. Hub Centres
3. Some DGH spokes
4. Home therapy services for immunoglobulin and C1 inhibitor replacement

7. Is the scope based on factors that can be objectively measured? What are the objective measures?

Yes:

For example

1. Patient satisfaction surveys and patient related outcomes measures
2. Survey of treatment centres with regards to compliance with consensus recommended treatments, professional standards and UKPIN standards
3. Delay in diagnosis/misdiagnosis data
4. Increased quality of life measures
5. UK PIN guideline compliance
6. Immunoglobulin Demand Management Plan Compliance
7. Successful UKPIN accreditation
8. Audit across networks and nationally
9. Equity of access to consensus recommended treatment (C1 inhibitor)
10. Equity of access to recommended levels of medication (C1 inhibitor)
11. Workload data capture via local and national databases

7. What are the consequences of introducing the scope? For example: including activity that is not specialised, excluding specialised activity that takes place outside of specialised centres, excluding activity that takes place in outreach clinics.

The consequences of introducing scope are:

1. It will clarify the fact that all PIDs are specialist conditions that need specialist services commissioned centrally with equity and excellence.
2. There are few remaining single handed practices – accreditation and quality standards can drive up quality
3. Harmonise care and management of PID
4. Improve networking
5. Reduce variation in care and costs
6. Increased quality of care
7. improved governance
8. improved monitoring of home therapy immunoglobulin replacement
9. Streamlined process reducing IFR burden on patients, commissioners and services

8. Are there any financial consequences of introducing the scope? For example, loss of income for providers that would no longer be considered to be specialised.

The scope describes the current level of service. No additional infrastructure or staff costs are envisaged with appropriate networking and effective use of resource.

It could result in a more cost efficient, stream lined service providing better services and quality of life for patients. It would certainly reduce variation.

Central commissioning could avoid excessive costs associated with inappropriate management of these complex but rare conditions e.g. delayed diagnosis, unnecessary procedures in hospital, A and E costs and even ITU costs.

9. Please describe any political consequences of introducing the scope? For example, exclusion of providers who deliver a specialised service within an

otherwise non-specialised setting or unhappiness amongst patient groups.

A few centres may be unable to meet the accreditation or quality standards and may have to cease delivering specialised services unless they can achieve them.

We foresee no political fall out of adopting this as a commissioned service and service providers would remain unchanged. There is potential to increase equity of access to treatment which leads to patient satisfaction.

PID is currently managed in specialised centres exclusively. Some C1inh care is undertaken in other centres but could be referred on to specialist centres as a result of a national policy.

Patient representatives on the CRG are fully in support of national commissioning.

10. Would the scope benefit or disbenefit particular CCGs? For example, if non-specialised activity was included because it takes place within a tertiary centre, would the CCGs that refer to that centre benefit. What would be the impact of the scope on technologies/drugs that are currently often commissioned through individual funding requests?

No obvious inequitable benefits that we can see.

Funding would not fall disproportionately to any particular CCGs responsible for a cluster of patients with high cost medication. Costing would form a small percentage of the national budget.

There is no issue about non-specialised activity being cross-subsidised utilising the proposed activity costing mechanisms, although clearly lead CCGs would have to ensure that resource was distributed effectively to cover service costs across their patch

11. Please describe any complexities in introducing the scope. For example, if the service is not currently commissioned by SCGs, will it be very difficult to assess the current level of spend on the service?

Immunoglobulin and IFR/biologic drug costs are easy to determine.

Workload data can be captured now and systems developed to capture increased detail in future.

Most of the infrastructure to support quality dashboards is in place once one is devised.

Home therapy service costs are not currently fully captured as it is a home service delivered through a hospital and no agreed policy on funding this currently exists. This process can address this.

Coding needs to be improved and year of care tariffs may provide a solution.

12. Is this an 'interim' scope? What could practically be done to refine the scope so that it better differentiated between directly commissioned services and those commissioned by CCGs?

This is the final scope addressing initial feedback.

The proposed scope does not involve any major redefinition of service speciality as all PIDs are currently managed solely by specialist services.

13. Is there anything else that you think the Clinical Advisory Group should know about the scope?

The clinical immunology community are willing to develop new models of care to ensure equity and excellence supported by national policy and a commissioning strategy with the support and input of patient groups.

We believe we have now provided a practical solution to enable accurate workload and activity data capture, as well as a mechanism for quality improvement and harmonisation for the service.

FEEDBACK

This process will need to be used to develop service scopes for all other specialised services. Please use this space to provide feedback on any ways in which the process could be improved.

Obviously the process was given insufficient time and resource to enable full consultation or detailed consideration of the initial scope. Further stages need better information and detailed feedback at an earlier stage to enable better and more effective engagement.

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