



PIN

PRIMARY IMMUNODEFICIENCY NETWORK

NEWSLETTER VOLUME 3 ISSUE 1 AUTUMN 2002

ADVERSE REACTIONS TO IMMUNOGLOBULINS

Following discussions at the RCN immunology nurses meeting in Cambridge at the end of February this year, it was agreed to have a working party to improve national reporting of adverse reactions to immunoglobulin for patients on home therapy. The objectives of the working party are:

- To make current adverse reaction form more user friendly
- To improve reporting procedure and awareness
- To enable audit of Epipen® use
- To open debate about patient education requirements and ensure evidence based practice
- To define the role of the adverse reaction co-ordinator

The Working Party: Caroline O'Grady, Karen Henderson, Sheila Cochrane, Cilla Freud, Peter Vickers, Fran Ashworth, Jo Harvey, Barbara Boardman.

PROPOSED ROLES AND RESPONSIBILITIES OF THE ADVERSE REACTIONS CO-ORDINATOR

- Collate and store adverse reaction forms
- Date and sign received forms
- On receiving three reaction forms for same product and batch number within any time frame: to discuss with product manager for the Company; alert UK-PIN Office and discuss action plan with Chairman
- Accountable to Chairman, UK-PIN
- Present an audit of reaction forms at biennial UK Immunology Forum

In particular we would like your opinion on the responsibilities of the co-ordinator.

Draft copies of the forms are available from Caroline O'Grady or from Olga Bryce in the UK-PIN Office [olga.bryce2@nuth.northy.nhs.uk]. We look forward to receiving your comments as soon as possible

Caroline O'Grady, Immunology Nurse Specialist
Christopher Andrews Ward
3rd Floor KGV Block
St Bartholomew's Hospital
West Smithfield
London, EC1A 7BE

CONSULTANT EXCHANGE

UK-PIN and the PiA have arranged for a scheme to permit consultant exchanges. This is aimed mainly at single-handed consultants initially and will permit them a sabbatical period at another recognised Primary Immunodeficiency Centre in the UK. The scheme has been funded by the PiA and the support will cover the travelling costs as well as costs of providing locum cover.

This is being advertised in the BSI Newsletter and the ACP Bulletin, but anyone who is interested can get further information and an application form from the UK-PIN Office [olga.bryce2@nuth.northy.nhs.uk].

HYPER IgE SYNDROME: WHICH GENE RESPONSIBLE?

In collaboration with Professor William Cookson at Oxford, the departments of Dermatology and Immunology at Great Ormond Street Hospital are keen on trying to identify the gene responsible for this syndrome. The gene responsible for hyper IgE syndrome has been located to a region of chromosome 4p approximately 64-72cM from the beginning of the chromosome. Atopy and total serum IgE levels have been linked to the same region in three studies.

This project will not only provide a better insight into this complex disorder but may also take forward our understanding of atopic disorders and regulation of IgE synthesis. We would be most interested to hear from immunologists who have definite cases and to obtain samples from

the cases and from both affected and unaffected family members. These would be used for linkage mapping and gene expression analyses on DNA microarrays.

If anyone has an interest in this please don't hesitate to contact me. We would ask you to complete a (relatively short) clinical questionnaire and to send blood samples. All collaborators would be acknowledged in any publications which might ensue.

Graham Davies
Great Ormond Street Hospital, London
davieg1@gosh.nhs.uk

Welcome to another edition of the UK-PIN Newsletter. I think you will agree when you read through that there is now a great deal happening on the immunodeficiency front and that UK-PIN is getting to grips with the key issues. The Steering Group meets twice yearly and has joint meetings with the PIA. We are nearing the end of the pilot phase of accreditation inspections and will be looking to appoint some additional inspectors later in the year. We remain extremely grateful to BPL for their continued support for the UK-PIN Office and for supporting this Newsletter.

We are keen to hear from readers and we are happy to publish brief letters or articles. Bear in mind that we only publish twice a year, so you will not get a speedy turnaround! Please can you ensure that all correspondence for UK-PIN is sent to Olga in the Office: she will ensure that it is forwarded to an appropriate person for a response. Remember that Olga also needs to know where people are to keep the mailing list current: if you don't tell us when you move we won't necessarily be able to guess! Where possible please give Olga your email address, as we wish to build up a system for sending out important information electronically.

Please think about ESID – a good showing from the British would be welcome and don't forget the Clinical Immunology sessions at the BSI/BSACI meeting at the end of the year.

NATIONAL PRIMARY IMMUNODEFICIENCY REGISTER

Following the meeting in York in the autumn, a reconvened steering group has been set up to consider options for on the way forward. This group comprises of Dr Graham Davies (London), Dr Louise Parker (Reader in Epidemiology Newcastle), Dr Carrock Sewell (Scunthorpe), Dr Paul Williams (Cardiff), Dr Mark Gompels (Bristol), Dr Jimmy Gooi (Leeds), Mr Kieran Benton (Database Specialist London), Mr David Watters (PIA). The steering committee has considered four options:

1. No change, stick with the Gracie Fields register.
2. Develop a new database from scratch to suit our purposes.
3. Adapt existing web based database with central reporting via the web (as proposed in the meeting at York)
4. Use the existing database but develop multiple satellite databases at each participating centre adapted to suit local needs with a common core data set which is down loaded to the central register.

There was unanimous support for option 4, which was also the favoured option in the feedback received at York.

There was been wide ranging discussion centreing on a paper provided for the steering group by Carrock Sewell. The questions that were discussed included the following:

1. What is the database for?
2. What would be recorded in the database particularly with regards data protection, issues of consent and issues of data validation?
3. Which data fields would be employed at either local satellite level and in the central register?
4. How would the database be managed and who would own the data?
5. Which format should be used for the database itself?

At the end of discussions the key points that emerged were:

- It would be essential to get informed consent from patients.
- The central register should be kept as simple as possible.
- The use of local (satellite) databases could contain many more datasets according to local need and could be used for patient management. They could be tied in with UK-PIN accreditation.
- The ownership of the data would, in this system, be distributed throughout all the UK-PIN users.
- A full time data manager would be required.

In the meantime some limited funding has been obtained from NSCAG to enable registration of all data on SCID (and other NSCAG funded) patients undergoing bone marrow transplantation at Newcastle General and Great

Ormond Street Hospitals. This project would involve satellite databases at the two centres with downloading of core data to a central server and to the European and International Bone Marrow Transplantation Registries. The local datasets will be geared to bone marrow transplantation, though there will be overlap with the data that would be required for a national UK-PIN immunodeficiency register. Further work will therefore be needed on datasets for the latter.

In response to a call for applications to establish or maintain disease registers for research purposes, a proposal for funding has been submitted to the Department of Health to establish the national register. The proposal is for four years funding to commence in January 2003. Initially, satellite databases will be established in six centres around the UK (Great Ormond Street Hospital, St Bartholomew's Hospital, Newcastle, Leeds, Cardiff and Bristol) with a common core data set held on the main server at the Institute of Child Health. It is proposed that these centres will be up and running within two and a half years of commencement of funding. For the final 18 months of the project satellite databases will be established at all the other UK centres for Primary Immunodeficiency. At the end of the period of funding it would be expected that all the major primary immunodeficiency centres in the UK will have satellite databases used in patient management and adapted to local needs with a common core data set which is automatically and regularly downloaded to the central server. The central core data set would be kept very simple but would be sufficient to allow research and audit projects to be initiated on a national basis. The funding is to provide the infrastructure for research projects, but the research itself will require separate funding applications. At the end of the four-year period it will be expected that maintenance of the database and its management would be funded by ongoing research grant proposals which require the use of the national register.

A response from the Department of Health should be available by the early autumn. In the meantime the steering group will be working on finalising data sets, obtaining LREC and MREC approvals and ensuring that all issues of data protection are adequately addressed. Any comments or offers of help will be gratefully received and should be sent to either Graham Davies or Carrock Sewell (davig1@gosh.nhs.uk or Carrock.Sewell@nlg.nhs.uk)

Graham Davies
Great Ormond Street Hospital
London

STEERING COMMITTEE: UK-PIN ACCREDITATION ON THE HORIZON

UK-PIN accreditation is moving slowly, but tortoise like we will get there, learning some valuable lessons along the way. We have now completed 3 visits with 2 outstanding – assessors identified and visits will be arranged shortly – and more application forms coming in. The preparation for the visits seems to be (reassuringly) about the same for each centre and the actual visit has taken 1.5 days on each occasion. So far, all involved have enjoyed the experience or at least found it worthwhile and encouraging. The initial concept of one doctor and one nurse seems to work well, though at present there is also a team leader who is CPA trained, in the long run this should not be necessary as it only adds to the expense. We are still on course for going live sometime in 2003 and the main item for the next Steering Group will be this implementation.

Olga is back in the UK-PIN office, after a period of ill-health and is doing an excellent job of co-ordinating the visits, forms etc. Tim has now trained additional assessors, both nursing and medical. During the inspections, the meetings with managers and pharmacies, which give the whole exercise some objectivity, have gone well. We still need to finalise how best to collect the patients' views, getting more returns and face to face discussions rather than pure paper work. We are working on this with the PiA.

There has been a lot of interest from the London Commissioners about accreditation. Those who were at the meeting in York last year will remember Paul Chiles contributing to our discussions. This has been useful in terms of credibility and moving forward on the implementation of definition 16 - Clinical Immunology with Susan Schonfield. All new changes are slow to implement and this "re-organisation" is no exception, especially for specialist areas in the face of the overall NHS philosophy, orientated to general services and PCTs. We have to have patience and keep moving forward bit by bit. Maybe we should collect an update of progress of specialist commissioning for Clinical Immunology throughout England later in the year? In the meantime if you have made some real progress in your area, do let us know and share it with the rest of us - Olga would be willing to do an email newsletter with any good news (as the RCPATH has done so effectively).

Other projects are coming on too. Matthew Helbert has set up a protocols working party and has already had 2 meetings. They have prioritised one guideline and three protocols to start with and are well on the way to producing some drafts. Next we need a website for colleagues to view the output and to facilitate feedback - any volunteers please? Matthew is also liaising with the CJD Surveillance Unit and others to improve ways of collecting data about transmissibility or otherwise of TSEs in blood products. This is a delicate issue about which there are many, often conflicting, views. Matthew's expert diplomacy enables these discussions and we hope that this will be able to make progress after his move to Manchester.

In another diplomatic effort, Alison Jones has agreed to lead a pharmaceutical liaison group. She will produce a draft scheme (for consultation) by means of which we can register our patients with the company which produce the relevant therapy for each individual. The PiA have agreed this approach and the companies have welcomed this as an adjunct to ensuring adequate supplies to avoid switching products (not in the patients' or the companies' interests in the long run).

Mark Gompels has agreed to take forward a consensus group for hereditary angioedema. The process is now under way and Mark is approaching potential volunteers for assistance. As you will have heard, Baxter-Immuno are withdrawing their C1-inhibitor concentrate later this year, but have negotiated with

Aventis for the Behring product [Berinert] to be made available, so there should be no gap in supply. There has also been concern over the partial withdrawal of Stanazolol, although for the time being it is still possible to import from Spain and the USA.

Richard Herriot has been working with the British Thoracic Society on guidelines for the investigation and management of bronchiectasis. This will be a useful professional link for UK-PIN. In other news, Graham Davies and others have put together, at short notice as always, a bid for the new UK-PID register, to increase the capacity and ease of extraction of timely and useful data. The Gracie-Fields register did an excellent job, copied all over Europe (what better compliment) but needs to be able to give ongoing data, and to fit with the new international diagnostic criteria. They envisage a network of local databases, allowing maximum flexibility (see Graham's report opposite).

Finally, thanks to the PiA, we are able to launch the new Consultant Sabbatical/ Exchange programme (see advert on page 1). This is not intended to supplement study leave but is aimed initially at single-handed consultants as a method of sharing good practice. The scheme could be expanded to specialist nurses if the pilot is a success but at present Trusts do provide funds for nurses to attend courses and expenses for visits to other centres when travel is needed. Trainees are not covered by this scheme; their secondments for training are covered by Deanery monies or Trusts. This scheme has been devised as there is no other way to provide protected time for consultants to go to another UK centre, and such sharing of ideas is vital, in view of excessive increases in workload.

Gavin is well into organising the 2003 forum - see below. Remember that the ESID scientific meeting is this year in October in Weimar. An education session on the 16/17th, an Ig symposium on the early evening of 17th and then to the Welcome party - please check the web site: www.esid.org. See you in Weimar!

UK-PIN IMMUNOLOGY FORUM – 2003

Plans are proceeding for the next Immunology Forum on 7th-8th November 2003. The meeting will be held as before in York, as this venue scored highly in the evaluation. AdOration will again be responsible for the logistics, with Tracy Dance and David Gunther who ran the last meeting so efficiently. Tracy is currently off on maternity leave [a problem that seems to afflict anyone who works with the Newcastle bunch!] but will be back by Christmas. The meeting will be an open, and there will be a charge, although we aim to offset the costs as much as possible by sponsorship. We intend to keep the costs low for Nurses, as we know that not all Trusts are good at funding study leave for Nurses. The programme and request for registration will be sent out after Christmas. We again want posters from trainees and nurses [not limited to immunodeficiency] and this time are happy to have posters on immunodeficiency from all other participants.

There will be a session for interesting case presentations. I have some specific requests:

- If you know of any new recruits [nurses, trainees, consultants], please let Olga know in the Office so we can update the mailing list.
- If you move please let Olga know too.
- If you have any contacts for sponsorship please let me know asap!
- We want senior immunology laboratory staff to come: please let Olga know about key people in your centre so we can make sure that they are put on the mailing list.

Organising Committee: Gavin Spickett [chairman], Cilla Freud, Andy Gennery, Lisa Wright, Matt Buckland, Bobby Gaspar, Teresa Green.

DUAL CERTIFICATION - SAC RESPONDS

Feelings are clearly running high about the current situation regarding Dual Certification in Immunology and another specialty. The article in the December 2001 issue of the UK PIN Newsletter contains some inaccuracies, which need to be clarified.

The first point to make is that all of us are training in order to provide high quality and appropriate services to people with allergic and immunological disease. In return, the NHS and the tax payer gives us the opportunity to work in an exciting and interesting area of medicine and to help a group of patients ranging from those with very minor symptoms through to people with life threatening disorders. Care for people with allergic diseases is mainly given in the community and indeed, many people with allergic disease do not come near a medically trained person but self medicate or use remedies recommended by friends, pharmacists etc. Specialist allergy services are currently rather uneven and may be provided in district and teaching hospitals by a wide variety of staff. Provided these staff recognise which sort of patients they can deal with and which they need to consult on, it does not matter whether their primary training is in Immunology, Allergy, Respiratory Medicine, Gastroenterology, Paediatrics, ENT, Dermatology, Renal Medicine or whatever. Similar considerations apply to patients with immunological disease, many of whom will be managed by primary care practitioners but those with more serious problems may require input from Rheumatologists, Nephrologists, Respiratory Specialists, Immunologists etc. Again, the key is to recognise what you are competent to deal with and consult when things get difficult.

Specialist certification is a means of demonstrating that the trainee has achieved sufficient expertise that they can be called a Specialist. This certification is required before you can apply for a consultant post, but most trainees will have a variety of other experiences over and above the minimum that they need to obtain their CCST. Depending on personal interests and their additional expertise, they may be more or less eligible for any particular post that is advertised. The basic principle behind the current CCST scheme and its interpretation by the STA is that you must have a CCST in something before you can become a consultant but possession of that CCST does not guarantee you a consultant post and neither does it mean that only people with a particular CCST can apply for a particular job. This means that when writing job descriptions for posts, it is customary to write that it is essential that the individual is on the specialist register and it is desirable but not essential, that their CCST should be in a particular area. This means that the appointment committee only looks at people who are

on the specialist register but then uses its discretion to decide which of the people that are interested in the job is most suited to the particular post in question.

There are some special problems in the area of Allergy and Clinical Immunology, not least because the name of the specialty and the name of the training programme has changed rather a lot over the years. From a strictly technical point of view, it was only possible to obtain a CCST in Allergy if you started higher medical training after June 1999. The STA have taken a fairly liberal view on allowing existing trainees whose training was clearly in Allergy as opposed to Immunopathology, to go forward and be awarded a CCST in Allergy. However, people whose training is primarily in Immunology/ Immunopathology and who are eligible to obtain a CCST in Immunology and were in post before June 1999, have not been allowed to re-register for an Allergy CCST. The SAC in Immunology and Allergy has spent a lot of time over the last few years helping individual trainees who have, through no particular fault of their own, found themselves in unusual difficult situations regarding registration. With effect from June 1999, it has been possible for hospitals and deaneries to put together training programmes for dual certification in Immunology and Allergy. At present one trainee has been appointed to such a programme and is registered with the JCHMT as such. It is also possible for people who have started training in Immunology to resign their post and obtain another post, which would enable them to acquire dual certification. However, it is not possible for people who were appointed to an Immunology training post and who wish to continue in their existing post, to try and play the system so that they can now become eligible for a dual certification when their training programme was not designed for this.

I know that many Immunology trainees feel that they are providing quite a large amount of Allergy service workload. It is of course perfectly right that Immunology trainees should have experience of treating patients with allergic conditions, just as they should have experience in Rheumatology, Nephrology, Infectious Diseases, Laboratory Management etc. This is regarded as useful experience towards their CCST in Immunology but is not going to be something that they can turn into a CCST in Allergy if they have not been appointed to a programme which allows them to do that. Any individual trainees who have difficulty with this or who feel that they want to argue the matter, are welcome to get in touch with me and I will be pleased to clarify any remaining doubts that they may have.

A J Frew
Professor of Allergy and Respiratory Medicine
SAC Chairman

CONTACTING UK-PIN

Correspondence for UK-PIN and the Steering Committee should be addressed to:

Olga Bryce
Secretary UK-PIN
Regional Department of Immunology
Royal Victoria Infirmary
Newcastle upon Tyne NE1 4LP
Tel: 0191 2820721 Fax: 0191 2275071
Email: olga.bryce2@nuth.northy.nhs.uk
(Please note change of email)

Editors:

Gavin Spickett, Consultant Clinical Immunologist.
Email: Gavin.Spickett@nuth.northy.nhs.uk
Tel. 0191 2825517
Teresa Green, Senior Immunology Nurse Specialist
Email: Teresa.Green@nuth.northy.nhs.uk
Tel 0191 2824770
Lisa Wright, Immunology Nurse Specialist
Email: Lisa.Wright@nuth.northy.nhs.uk
Tel 0191 2824770

Sponsored by an Educational Grant from
Bio Products Laboratory.

The views expressed in this newsletter are not necessarily those of BPL.

Published by:
Oyster Healthcare Communications Ltd,
42 Hartington Road, Brighton, East Sussex
BN2 3LS.
Tel 01273 601996.
Email: mail@oysterhc.co.uk