Minutes of UK PIN Meeting with the PIA
Held on 18 March 2003 at the MRC Clinical Trials Unit

Present: **PiA**

Mr David Watters

UK PIN

Dr Helen Chapel
Dr Gavin Spickett
Dr Timothy Wallington
Dr David Webster
Dr Matthew Helbert
Dr Alison Jones
Sister Veronica Brennan
Sister Fran Ashworth
Sister Teresa Green
Mrs Olga Bryce

Apologies: Mrs. Clare Tritton
Dr Amolak Bansal
Dr Graham Davies
Dr Richard Herriot

Agenda Item	Action
Item PIA/01/03 Apologies for Absence Apologies for absence were made for Ms Clare Tritton, Dr Amolak Bansal, Dr Graham Davies and Dr Richard Herriot	
Item PIA/02/03 Matters Arising From Previous Meeting ***PIA/02/03(a) Consent Form – Patients Views*** General agreement consent is obtained but there are variations of how they are written as hospitals have their own views on consent. Some consent is based on DoH standard documents and the PIA have been asked to put something in the newsletter about change and variations in the DoH form. Helen Chapel is to prepare a short document to give to David Watters at the AGM meeting. There is no retrospective consent required for past infusions but there will be prospective consent for those already on treatment for infusions. Advice to be included on Website.	 **D Watters (PIA)** **H Chapel (UK PIN)** **Gavin Spickett**

Item PIA/02/03(b) Sample Register Doctors Eglin and Anstee have been approached by UKPIN (HC letter after EMEA meeting in November 2002) to add samples from PID patients but we are still waiting to hear from them.	**G Spickett (UKPIN)**
Item PIA/02/03(c) Specialist Services <u>Specialist Commissioning:</u> Despite returns from UKPIN and the PiA, to the consultation questions re specialist commissioning, there was no mention of PIDs in the overall responses document. Neither is there mention of Clinical Immunology (definition 16) in the recently distributed Guidance. Helen Chapel has expressed concern to Julia Stallibrass whose response was that the examples given were only to illustrate but were not comprehensive; HC will contact Mike Gill re final guidance. <u>London</u> London commissioning will be starting in April 2003 in a very basic way. Susan Schonfield had expressed the view that UK PIN would have an important role to play in terms of accreditation. Key features of discussions with her related to: • Costings per centre should be accurate and give activity as well as trends • Activity – a minimum for expertise and it might be helpful to have standards for Associated centres • Collaboration – she was impressed by the collaborative approach taken by Immunologists in London. <u>Oxford</u> Oxford have the interest of the local Commissioners [LSCG] and HC and the Service Manager sit on the LSCG Immunology Advisory Group. Key features are: • IVIG Panel to help PCTs understand and monitor the usage of IVIg in PIDs and for immune modulation; it is hoped that this will provide a mechanism / process for funding. • Activity Data for immunomodulatory and replacement Ig, by means of an annual audit by hospital pharmacists in all DGHs in the StHA patch. <u>West Midlands, S West, Wales, Trent</u> , <u>S East,</u> to find out what is happening <u>Northern</u> will be adopting the hub and spoke model for PID accreditation <u>North West</u> has a Clinical Governance Network but no financial process	**H Chapel (UK PIN)** to forward by email to the Steering Group. Contact Mike Gill[1] **H Chapel (UK PIN)** **H Chapel (UK PIN)** **Helen Chapel try to draw this together by June 2003.**

[1] guidance is generic and examples are truly that. He suggests that we need to identify another PHM consultant to take a lead, to develop a process for getting PCTs together and provide a national model.

<u>Role of UKPIN / PiA in Specialist Commissioning:</u> • Helen Chapel to liaise with David Watters re "Road show as per Medicine for Managers" as suggested by SS • Commissioners will want to use the website – need to identify a web master / train Olga • Website – ask Carrock how to add a "news" section and who should liaise with PiA As part of Specialised Commissioning and in relation to better blood transfusion in 2000. The Hospital Transfusion Committees may provide models for monitoring IVIG. Helen Chapel will speak to Mike Murphy. UK PIN to consider revising pharmacy standards for IVIG continuity of supply	**D Watters (PIA)** **H Chapel (UK PIN)** **G Spickett (UKPIN)** **H Chapel (UK PIN)** **H Chapel (UK PIN)**
PIA/02/03(d) HAE Consensus The HAE Consensus document is well underway led by Mark Gompels. They will report to the PIA MAP in summer of 2003. at a meeting to be arranged.	**D Watters (PIA)**
PIA/02/03(e) Primary Antibody Deficiency (PAD)Consensus UK PIN – to produce document on PAD, with evidence based documents and sections for education of patients and doctors. This is evidence based in collaboration with UK PIN's Protocol Group & Cochrane database Consensus document [1994] being revised by Mohammed Ibrahim, Matthew Helbert, Amolak Bansal, Mike Duddridge and Helen Chapel. • Some sections can be done by trainees as an educational exercise • to liaise with NSCAG centres for rare diseases & BMTx • may form the basis for a National Service Framework • arrange next meeting • contact Dave Roberts in Oxford about the link to the Cochrane database	**H Chapel (UK PIN)**

PIA/02/03(f) York Meeting Plans There will be reduced fees for nurses (sponsored by BPL). The PIA have offered financial support to meet sponsorship shortfall. A provisional program will be published in the next newsletter.	**D Watters (PIA)** **G Spickett (UKPIN)**
PIA/03/03 Consultant Exchange This "sharing good practice /exchange" scheme has been slow to start and it was suggested that it could include visits by UK PIN's Protocols Group. ***PIA/03/03(a) Enabling Visits to Europe by UK Specialists*** It was agreed that funding from the PIA is for the UK only. Lack of applicants is due to the workload of the consultants. ***PIA/03/03(b) Extending the Scheme to Immunology Nurses*** It was agreed that the scheme should be widened to include nurses. Teresa Green and Fran Ashworth are to look at the needs and suggestions for the visits for the nurses Matthew Helbert and Richard Herriot will do the same for the medical staff and will revise the documentation to stress: • support for CPD, • choice to request a visitor for help with protocols • encourage individual lone consultants to use the exchange scheme	**T Green (UK PIN)** **F Ashworth (UK PIN)** **M Helbert (UK PIN)** **R Herriot (UK PIN)**
PIA/04/03 Timing of Patient Questionnaires for Accreditation Visits ***PIA/04/03(a) Format of Patient Questionnaires*** Patient questionnaires have had varied responses sometimes disappointing. To make this a real part of accreditation, a small group of patients plus Sheila Cochrane and a paediatric nurse eg. Lucia Russell from Newcastle General Hospital to be asked to review. Helen Chapel will send papers relating to the review of the scheme by Oxford patients to David Watters ***PIA/04/03(b) Trained Patient Inspectors*** There is also a need to explore their use in other medical specialities[2]**.** Who would train them, how and why. ? Divide technical standards from patient standards	**D Watters (PIA)** **H Chapel (UK PIN)** **David Watters (PIA)** **M Helbert (UKPIN)**

[2] variable - Haemophilia Soc has patients getting training and then participating in writing NSFs http://www.haemophilia.org.uk/publications/hqspring2002.pdf
British Thoracic Society / Cystic Fibrosis - no patient involvement. BHIVA - no involvement

PIA/05/03 Website UK PIN is registered as a domain name and **the target date for an operational website is the end of May.** It is crucial UK PIN website and PIN Guideline website are linked to the PIA website. Olga would need some training re web site management etc Carrock to be invited to Newcastle to meet Olga and review needs David Watters is to invite Carrock Sewell to meet with John Satchell at the PIA for discussion	**G Spickett (UKPIN)** **O Bryce (UKPIN)** **D Watters (PIA)**
PIA/07/03 Immunoglobulin Register The Chairman thanked Alison Jones for taking the lead on the liaison with the manufacturers and for organising the Ig register. We should also thank the staff in the centres for providing this info so promptly. Trends will become apparent over several years. it was agreed that the audit should be annual. The question now remains as to how to make best use of it, as a tool for ensuring Ig availability – to be discussed within the Industry Liaison group (by email) & report back to SC in July. It was agreed that the Immunoglobulin Register is a highly confidential document and must, therefore, be deleted from everyone's email and hard copies either returned to Olga Bryce or shredded.	**O Bryce (UKPIN)** **AlisonJones (UKPIN)** **O Bryce (UK PIN)**
PIA/08/03 IVIG The national tendering exercise is still under discussion through the Purchasing and Supply Agency (PASA). London tendering is under active discussion – clarification needed Helen Chapel and David Watters to get in touch with PASA; Charles Lister is leaving so it will be his replacement. We should invite him /her to the next meeting of PiA/UKPIN	**H Chapel (UK PIN)** **D Watters (PIA)** **O Bryce (UKPIN)**
PIA/09/03 Paediatric Immunology –information David Watters raised concerns about Paediatric Immunology in Birmingham which were noted	
PIA/10/03 Research in CVID -information Following the Coughton Court meeting, proposals have been submitted for a major multi-centre CVID research network which would be open to all. The process is under active discussion with a funding body and is currently led by Professor Lennart Hammarstrom.	

PIA/11/03 Prions in IVIG -information Matthew Helbert reported on the establishment of a database of patients exposed to potentially contaminated IVIG [3]. This will have implications for the advice which will come from the vCJD Expert Panel shortly. We need, with PiA, to be in a position to advise those affected.	**D Watters (PiA)** **M Helbert (UKPIN)**

[3] REPORT ON Vcjd INCIDENTS PANEL MEETING 10.4.03
Since the last meeting 18 months ago, the panel has been incorporating comments to the Framework Document 'Management of possible exposure to CJD through medical procedures'. The panel also now has access to a new risk assessment, commissioned from Det Norske Veritas, 'Risk assessment of exposure to vCJD infectivity in blood and blood products'. This takes into account new animal data on blood borne transmission and has revised some of the mathematical modelling. The new risk assessment gives two levels of possible infectivity for IVIg. These are:

Pessimistic	9.1×10^{-5} ID_{50}/g	about 1:10,000 risk per g of immunoglobulin.
Optimistic	8.4×10^{-6} ID_{50}/g	about 1:100,000 risk per g of immunoglobulin.

These models have to be seen in the light of continued absence of human-to-human spread through blood or blood products.

The framework document had identified two types of risk category. The low risk category was for all patients who were exposed to UK sourced blood products in 1997/98. These individuals would have data entered on a confidential database, without consent, although the option for opting out existed. This research / surveillance proposal is not to be actioned for the time being, pending further consultation.

The second category is for patients at higher risk, because of exposure to potentially contaminated batches and individual dose of immunoglobulin. These individuals are thought to require both identification and contacting, because of possible public health risks through surgical procedures. There are thought to be overwhelming risk assessment arguments for identifying the *contactable group.*

A substantial part of the rest of the meeting was spent discussing the exposure risk cut-off for the contactable group. The option to have no cut-off, and apply special precautions to all immunoglobulin recipients, was deemed untenable because it would imply all anti D recipients, for example, should be identified.

Two arguments for adopting the pessimistic model and a cut-off of 1% risk were presented. The first was that the surgical instrument and NBA models have used the pessimistic model and consistency may be important (even if not based on evidence). The second is that it is easier to be pessimistic initially and then more relaxed, in the light of emerging data, than vice versa.

This approach means that any patient exposed to more than 300g per year of potentially contaminated batches of Vigam or SNBTS Ig in 1997/98 would be placed in the contactable group.
About 130 PID patients were exposed to Vigam or SNBTS Ig in 1997/98, but we don't know how many received potentially contaminated batches (Matthew by telephone survey). The panel were told in very clear terms that we have no way of identifying non PID patients exposed to these products or whether batch documentation exists for this group. The other major group affected by this cut-off is haemophiliacs. This model is unlikely to affect recipients of other blood products (albumen, specific Ig).

No specific time line was identified for implementation of this process, which is outlined in section 5 of the framework document. Essentially, Manufacturers advise the Consultant responsible for Communicable Disease Control that a potentially infected product has been distributed to a Trust, the CCDC liases with the local specialist, who breaks the news to the patient. We obtained agreement that:

- That the patients' specialist team would break the news (not the local CCDC).
- That there would be resources for advance information and training for specialist teams and relevant NGOs.

PIA/12/03 Mycoplasma -information David Webster reported on concerns over the detection of Mycoplasma in clinical samples. The committee agreed that this issue needs to be explored on a wider basis within Europe. David Webster agreed to liaise with ESID about this.	**David Webster (UK PIN)**
PIA/13/03 Sister Veronica Brennan It was noted that this was Nicky Brennan's last meeting before her retirement. The Chairman thanked her for all her help and wished her well on her retirement on behalf of UK PIN,	
Date and Time of Next Meeting **The next Steering Group meeting will be held at 11.00 am on Tuesday 22 July 2003 at the MRC Clinical Trials Unit, 222 Euston Road, London, NW1 2NZ**	

- There would also be a campaign of public information, after discussion with specialists and NGOs.

Matthew Helbert

So we need to make a decision asap as to the process to adopt when the contactable group are contacted. These political decisions can happen very quickly and we don't want to be caught without a plan. Local specialists should break the news and that they may need "breaking bad news" training – should be offered it anyway. There is a role for the PiA here , to organise courses and for UKPIN to persuade colleagues to accept this – it would have been very useful to have such provision before the HCV outbreak in 1994.