PATIENT INFORMATION ADVISORY GROUP

Meeting on Monday 12 September 2005 at 10.30am

Minutes

1. Present

Members: Professor Joan Higgins (Chair), Dr Fiona Douglas, Ms Stephanie Ellis, Mr Michael Hake, Ms Ros Levenson, Ms Barbara Meredith, Professor Roy McClelland, Professor Sir Denis Pereira-Gray, Dr Peter Rutherford, Dr Michael Wilks.

In attendance: Mr Patrick Coyle, Ms Karen Thomson, Mrs Anne Ward, Miss Victoria Lowther, Mr Jim Shannon, Mrs Fiona Bisset.

Apologies

Apologies had been received from Professor Mike Catchpole, Dr Tricia Cresswell, Ms Julia Palca, Professor Martin Severs and Professor Peter Furness. Professor Furness had also indicated that he would have to resign from the Group, as he had been elected Vice President of the Royal College of Pathologists but was willing to continue until the end of November when he would take up his new post. The Secretariat were to give directions to the NHS Appointments Commission to find a replacement.

2. Minutes of last meeting

2.1 Minutes of the previous meeting held on the 7 June 2005 were agreed to be an accurate record.

3. Matters Arising/Action Points:

Application from Bolton, Salford and Trafford Mental Health NHS Trust – A National Case Register Activity within national commissioned Medium Secure Adolescent Forensic Services [PIAG 2-10 (h)/2005].

The Advisory Group considered additional information submitted by Bolton, Salford and Trafford Mental Health Trust as requested by the Advisory Group at their previous meeting. The Advisory Group were asked to consider whether it was acceptable for the applicants to hold identifiable data for 10 years.

The Advisory Group agreed that the study should be given full approval but that they should develop an exit strategy moving away from needing to retain identifiable information for so long. The Secretariat agreed that this should be a condition for their Annual Review.

ACTION: Applicant to be informed of the Group's decision.

Application from the Intensive Care National Audit and Research Centre (ICNARC) – Case Mix Programme [PIAG 2-10(f)/2005].

The Advisory Group considered additional information concerning the ICNARC project and were informed that Karen Thomson had met with the applicants to discuss their application. The Advisory Group agreed to approve the study subject to the following conditions:

- That they revise their patient information leaflets and posters so they have an impartial tone.
- That they provide the Secretariat with detailed lines of accountability for the project.
- That they develop an exit strategy with the NHS CFH Secondary Uses Service.

ACTION: Secretariat to inform the applicants of the Group's decision.

Request from the Confidential Enquiry into Maternal and Child Health (CEMACH)

The Advisory Group was asked to consider two separate issues extending the activities undertaken by CEMACH:

Firstly, in relation to their Maternal Death Enquiry, the applicants wished to extend their application to cover a detailed case note audit of all Maternal Suicides and Deaths from Psychiatric Causes for the period 2003-2005. The Advisory Group agreed to approve this extension as the applicants would be removing identifiers once initial collection process of the project was complete.

Secondly, the Advisory Group reviewed the further information provided in relation to the Child Death Review Project, considered at the previous meeting. The Applicants had responded to the Group's request to improve their user involvement and to take a different approach to the project when dealing with older children. The Group were satisfied with the response provided.

ACTION: Secretariat to inform the Applicants of the Group's decision.

4. UK Biobank briefing on the use of demographic data [PIAG 3-05/2005].

4.1 Tim Sprosen, Mike Pringle and Rory Collins attended the meeting to discuss the proposed draft protocol for the recruitment pilot for UK Biobank, which detailed the use of demographic data. The Advisory Group discussed the use of demographic information and were clear in their view that this information, whilst not sensitive in the way that clinical information would be, is given to the NHS with an expectation of non-discosure. Therefore, the provision of such information to an external body would be perceived by patients, as a breach of confidentiality. The Group agreed on the following two options for UK Biobank to consider:

- Firstly, to ask PCTs to write to their patients within a relevant age group, inviting them to participate in the UK Biobank project. This would therefore involve no disclosure of information prior to gaining consent.
- Otherwise, to apply for Section 60 support.

The Secretariat agreed to inform UK Biobank of these options and report to the next meeting.

5. Review of Information Governance and work of the Care Records Development Board

5.1 Harry Cayton was in attendance at the meeting to discuss his current work on reviewing Information Governance and the work of the Care Records Development Board (CRDB). He informed the Group that he was currently undertaking an Information Governance review on behalf of the CRDB, which would consider the findings and make recommendations in November. He informed the Advisory Group that the review covered the remit of advisory bodies and the current role of Caldicott Guardians. The Review was not yet complete but the Advisory Group were assured that they would see the final recommendations and findings when they are available.

6. Implementation of Secondary Uses Service

6.1 Jeremy Thorpe and Lisa Franklin were in attendance presented a series of slides on the implementation of the Secondary Uses Service (SUS). They informed the Advisory Group of the timescales involved in the delivery of SUS and some of the current issues it is facing. The Advisory Group agreed that it would be useful to have regular update on the development and implementation of the SUS. In light of the proposed timetable, it was agreed that pursuing Regulations to support the national databases such as HES and NWCS would not be an effective use of Parliamentary time. With respect to the Welsh database, PEDW, it was agreed the Secretariat should ask the WAG to consider whether they wished to bring forward Regulations separately once they had identified an exit strategy from Section 60 support.

Action: Secretariat to contact Welsh Assemby policy lead for this area.

7. Applications for Section 60 support

7.1 Glasgow University – Estimating the prevalence of problem opiate and problem ,cocaine use in England [3-07(b)/2005]a

The Advisory Group considered an application for Section 60 support from the University of Glasgow for a study into the prevalence of problem opiate and problem cocaine use in England. The applicants were unable to gain consent from the patients because they did not have their contact details and because the cohort were a difficult group to contact.

The Secretariat had gained advice from Department of Health solicitors on whether this application could go ahead given that the Section 60 regulations only cover

England and Wales. However, due to the fact that Glasgow University were completing the work on behalf of the National Treatment Agency, the Home Office and the Department of Health, it was agreed that these agencies should apply jointly and that the University should process the data on their behalf.

The Advisory Group agreed to approve the application subject to the following conditions:

- That the application form be resubmitted to reflect that Glasgow University are completing the project on behalf of the National Treatment Agency/Department of Health/Home Office.
- That there be an appropriate contractual arrangement in place between the NTA/DH/HO to comply with the Data Protection Act.
- That the applicants provide reassurance they are aware that the Official Secrets Act does not cover the proposed use of the data.
- That the applicants make steps to improve their user involvement.
- That the applicants submit a System Level IT Security Policy once the above arrangements are in place.

ACTION: Secretariat to inform the applicants of the Group's decision.

7.2 Northwest Institute for Bio-Health Informatics – Cardiac Rehabilitation Clinical Management System [PIAG 3-07(c)/2005]

The Advisory Group considered an application from Northwest Institute for Bio-health Informatics for a pilot study to evaluate the changes in working practice and service provision for cardiac rehabilitation services in Lancashire by creating an NHS net based rehabilitation information system.

Section 60 support was needed because some of the patients eligible to be on the database would be discharged before the opportunity to gain consent arises.

The Advisory Group requested that the applicants should complete the following work and re-submit to the next meeting:

- That the applicants be clearer and more specific as to the purpose of the application, in particular, how they are going to use the data obtained.
- That the applicants be more specific about when they will have arrangements in place to rely on obtaining patients consent.
- That the applicants elaborate on section (r) of the application form and explain in more detail how the system will comply with the Data Protection Act principles.
- That the applicants make more effort to involve service users.

ACTION: Secretariat to inform the applicants of the Group's decision.

7.3 University Hospital of Leicester NHS Trust – Ethnic Differences in Lung Function [PIAG 3-07(d)/2005]

The Advisory Group considered an application from the University Hospital of Leicester NHS Trust for a preliminary study to examine the hypothesis that male patients of Asian origin with Chronic Obstructive Pulmonary Disease have a worse lung function than their white counterparts of similar age and a steeper rate of decline of lung function.

Identifiable patient information was required as the applicants intended to use a validation technique of name analysis to ascertain the patients ethnicity.

The Advisory Group agreed to approve the study subject to the following conditions:

- That the study involves user groups including groups from appropriate ethnic communities and also to obtain specific feedback from user groups on the study methodology.
- That the applicants use age rather than date of birth.
- That the applicants consider a report by the Public Health Observatories on recording and determining ethnicity and the use of names.

ACTION: Secretariat to inform the applicants of the Group's decision.

The Advisory Group discussed the legal implications of accessing data collected a considerably long time previously. Mr Shannon agreed to look into this issue and report back to the Group.

ACTION: Mr Shannon to look into the legal implications of the use of data preceding the Data Protection Act and Section 60 Regulations.

7.4 University of Newcastle upon Tyne – Developing and evaluating the effectiveness of educational prompts in improving diabetes care [PIAG 3-07(e)/2005]

The Advisory Group considered an application from the University of Newcastle upon Tyne for a project to develop and evaluate the effectiveness of educational prompts in improving diabetes care. Section 60 support was required in order for the project to have as little impact and not alter the GPs behaviour.

The Advisory Group agreed to approve the application subject to the following conditions:

- That the applicants engage users groups in the project.
- The applicants produce a patient information leaflet for distribution which should also includes an opt out mechanism for those people who object to their data being used.

ACTION: Secretariat to inform the applicants of the Group's decision.

7.5 Queen Mary University of London – EPICure 2 Population based outcomes for births before 27 weeks gestational age in England in 2006 [PIAG 3-07(f)/2005]

The Advisory Group considered an application from Queen Mary University of London for the EPICure 2 study into the survival and clinical outcomes in neonatal morbidity in births at 22 to 26 completed weeks gestational age.

Section 60 support was required as the data would be collected in collaboration with the Confidential Enquiries into Maternal and Child Health (CEMACH) and the difficulties of seeking consent from newly bereaved parents .

The Advisory Group approved the application subject to the following conditions:

- That the applicants produce and distribute throughout the centres taking part, a patient information leaflet which includes information about opting out.
- That the applicants clarify when and how they anonymise the patient data.
- That the applicants consult with representative groups for bereaved parents.

ACTION: Secretariat to inform the applicants of the Group's decision.

7.6 University College London Medical School – Prognosis of coronary disease in different South Asian populations in Britain [PIAG 3-07(g)/2005]

The Advisory Group considered an application from the University College London Medical School for a study into the prognosis of coronary disease in different South Asian populations in Britain. Patient identifiable information would be required as this was a retrospective study of a large number of patients.

The Advisory Group requested that the applicants re-submit their application to the next meeting in December, with the following additional detail:

- Provide more clarity on the purposes of the study, where the data will be coming from, how it will be transferred and where it will be held.
- How they will determine the ethnicity of the patients.
- To involve user groups in the study.
- To provide more detail in questions (o) and (q) on the application form.

ACTION: Secretariat to inform the applicants of the Group's decision.

7.7 University of Cambridge – Hyperglycaemia and Outcome of pregnancy in Cambridge [PIAG 3-07(h)/2005]

The Advisory Group considered an application from the University of Cambridge for a study into hyperglycaemia and outcome of pregnancy in Cambridge. Section 60 support was required as there would be a large number of patients in the cohort.

The Advisory Group agreed to approve the application subject to the following conditions:

- That the applicant involve users groups in the project.
- The applicant provide more detail on how they meet the eight data protection principles.

- Complete a System Level IT Security Policy with detailed lines of accountability.
- That the applicants produce a patient information leaflet or an article for an appropriate patient publication and appropriate opt out mechanisms.

ACTION: Secretariat to inform the applicants of the Group's decision.

7.8 Great Ormond Street Hospital NHS Trust – Cardiac Transplant in Childhood Cancer Survivors; an update [PIAG 3-07(i)/2005]

The Advisory Group considered an application from Great Ormond Street Hospital NHS Trust for a study into cardiac transplant in childhood cancer survivors; an update. Section 60 support was required because of the large number of patients in the cohort.

The Advisory group agreed to approve the application subject to the applicant agreeing to undertake more user group involvement.

ACTION: Secretariat to inform the applicants of the Group's decision.

7.9 University of Oxford – The reliable evaluation for the effect of allogeneic stem cell transplant compared with chemotherapy in childhood acute lymphoblastic leukaemia [PIAG 2-10(j)/2005]

The Advisory Group considered an application for Section 60 support from the University of Oxford for a study into the reliable evaluation for the effect of allegeneic stem cell transplant compared with chemotherapy in childhood acute lyphoblastic leukaemia.

Section 60 support was required to link a large number of patients. The applicants were also concerned that obtaining consent from parents would cause unnecessary distress. The Advisory Group wondered if it would be feasible for the record linkage to be undertaken in a different way. For example if UK Transplant were to undertake the linkage and then only release data about patients falling into this cohort.

The Group agreed that approval of this study could be,undertaken by Chair's action following further discussion with the applicant.

7.10 University of Leeds – Health Facilitators and Learning Disability: Evaluating the Role of Health Facilitators [PIAG 3-07(k)/2005]

The Advisory Group considered an application from the University of Leeds for a study to evaluate the impact of health facilitation on the experience of people with learning disabilities.

Section 60 support was required as the applicant felt that gaining consent from the cohort would have been problematic.

The Advisory Group had a number of concerns with regard to this application and in particular gaining consent from the patients. Therefore, they requested that the

applicants resubmit their application to the next meeting addressing the following issues:

- That they demonstrate how they fit into the Valuing People strategy.
- That they develop a consent based exit strategy.
- That the first point of contact for the patients would be the treating clinician and not the researcher.
- That the applicants ensure that they have research ethics approval for the study.
- That they ensure that data transfer processes would be made secure.

ACTION: Secretariat to inform the applicants of the Group's decision.

7.11 University of Birmingham – Prostate specific antigen and prostate cancer linkage study [PIAG 3-07(l)/2005]

The Advisory Group considered an application for Section 60 support for a retrospective analysis of GP records from 30 practices in Birmingham and Solihull to prostate cancer registrations collected by the West Midlands Cancer Intelligence Unit.

Section 60 support was required as the study needed to use identifiers to link large number of patients.

The Advisory Group requested that the applicants resubmit their application after completing the following work:

- Provide more detail as to why they cannot obtain patients consent or use pseudonymised data for linkage.
- Revise the application form to demonstrate that they fully understand confidentiality principles.
- Involve users in the project.

ACTION: Secretariat to inform the applicants of the Group's decision.

7.12 National Cancer Services Analysis Team – Detailed clinical and geographical analysis of the existing Clinical Genetics Services in the NW of England [PIAG 3-07 (m)/2005].

The Advisory Group considered an application from the National Cancer Services Analysis Team for a detailed clinical and geographical analysis of the existing Clinical Genetics Services in the NW of England.
Section 60 support was required to link data about a large number of patients from pre-existing sources.

The Advisory Group agreed to approve the application providing the applicants ensure they have a robust mechanism to involve users in this project and all their other projects. In particular the user involvement should be relevant for the particular project.

ACTION: Secretariat to inform the applicants of the Group's decision.

7.13 University of York – Choice of Hospitals for elective referral [PIAG 3-07(n)/2005]

The Advisory Group considered an application from the University of York for a study to examine the factors influencing the choice of hospital for elective referrals from general practice. Section 60 support was required in order to use patients full postcode to determine patients distance to hospital.

The Advisory Group agreed to approve the application subject to the applicants gaining Research Ethics approval if the local committee decided it was necessary.

ACTION: Secretariat to inform the applicants of the Group's decision.

12. Any Other Business

12.1 The Advisory Group were informed that the Secretariat had moved offices and were advised of the new contact details.

13. Future meetings for 2005

13.1 The Advisory Group were informed that the next meeting would be held on the 7 December at the Radisson Grafton Hotel, Tottenham Court Road, London.

13.2 Dates for meetings in 2006 would be circulated after the meeting.