PIAG
2-02/2004

PATIENT INFORMATION ADVISORY GROUP

Meeting on Tuesday 2 March 2004

Minutes

1. Present

Members: Professor Joan Higgins (Chair), Professor Michael Catchpole, Mr Patrick Coyle, Dr Tricia Cresswell, Mrs Helen Darracott, Mr Michael Hake, Ms Barbara, Ms Helen Miller, Meredith, Ms Julia Palca, Professor Sir Denis Periera Gray, Mrs Shahwar Sadeque, Ms Karen Thomson and Dr Michael Wilks.

In attendance: Mr Patrick Coyle, Mr Peter Singleton, Mr Roger Richards, Mr Sean Kirwan, Miss Victoria Lowther.

2. Apologies

Apologies were received from: Professor Sir Cyril Chantler, Professor Martin Severs and Mr Phil Walker.

3. Minutes of last meeting

3.1 Minutes of the last meeting [PIAG 1-02/2004] that had taken place on 9 December 2003 were approved subject to some minor amendments.

4. Matters arising/action points

Revised Section 60 Regulations

4.1 Mr Kirwan reported that the public consultation on the draft revised regulations to be made under Section 60 had ended on 30 January. The Secretariat received 38 responses of which: 25 were supportive; 11 were opposed and 2 were neutral. A summary of the responses on the draft regulations was circulated in the Secretariat Report [PIAG 1-03/2004]. The majority of those who were opposed to the proposals were individuals or organisations representing GPs and, in the main, their opposition was based on a view that the revised regulations would allow patient information to be processed for new purposes rather than regulate activities that were already being undertaken by the NHS.

4.2 Mr Kirwan advised the Group that the Department of Health had recommended that the Advisory Group should delay making a decision on whether the draft regulations should be put before Parliament. This was because there was a strong likelihood that new systems to replace NWCS and NHAIS would be established within 12-18 months and that these would be able to provide anonymised/pseudonymised data to support the activities described in the proposed regulations; in addition, more time was required to review the information requirements of the new GMS contract. The Advisory Group agreed to defer the decision about the new regulations until its next meeting.

Commission for Healthcare Audit and Inspection - Access to Patient Records

4.3 The Advisory Group agreed that the Commission would play an essential role in improving the provision of healthcare by the NHS and that it had no interest in obstructing CHAI's work. However, the Advisory Group had previously expressed concerns about proposals to allow CHAI access to patient identifiable information. Partly in response to the concerns, a draft Code of Practice on access to patient records had been produced by CHAI (and had previously been circulated to the Advisory Group by Dr Wilks).

4.4 Although the Advisory Group believed that the draft Code of Practice established a structure that would provide openness, accountability and a commitment to review procedures, it identified several areas where amendment was required as follows:

- Para 7: The Advisory Group was concerned that the wording of this paragraph was particularly weak, and that there needed to be a stronger framework governing the circumstances in which CHAI can share information with other organisations
- Para 26: The Code needed to provide stronger guidance on using identifiable data about people who lack capacity to provide consent. The Advisory Group was of the view that CHAI should be driving improvements in this area rather than relying on existing guidance or advice from professional bodies.
- The Code needed to be clear that the use of identifiable data will be limited to activities where its use is absolutely essential and where it is not practicable to obtain consent or use anonymised information
- The Code needed to make it clear who would be responsible for obtaining patient consent to use identifiable information in circumstances where it would be practicable to do so

4.5 The Advisory Group would also welcome a commitment by CHAI to seek its advice before making changes to the Code following review (as described in paras 61-64). The Secretariat was asked to forward these comments to CHAI, with a request that the PIAG be formally consulted on the Code before it is implemented.

ACTION: Secretariat to forward the Advisory Group's comments on the draft Code of Practice to CHAI.

House of Lords Debate on Cancer Registration

4.6 Mr Kirwan reported that on 7 January the House of Lords held a debate on Cancer Registration. Several references were made to PIAG and Section 60. A copy of the Hansard extract had been appended to the Secretariat Report.

Letter from Professor Nick Day

4.7 Professor Higgins reported that she had received a letter from Professor Nick Day requesting the Advisory Group to endorse the following statement that had been agreed by an expert group of cancer researchers:

> *"Consent is not required for access to medical records for non-commercial medical research that will have no impact on the individuals being studied and that has been approved by an accredited research ethics committee."*

4.8 The Advisory Group agreed that it could not endorse the statement, as consent should be over-ridden only in quite specific circumstances and that appropriate arrangements needed to be established to ensure that access to identifiable data was restricted.

4.9 The Advisory Group also agreed that it needed to engage with the Cancer Research community to encourage dialogue and greater patient involvement in the future.

ACTION: Professor Higgins to respond to Professor Day.

Previous Applications for Section 60 Applications

4.10 The Advisory Group considered additional information that had been submitted in support of applications that had been discussed at previous meetings, as follows:

(i) Oxford Register of Early Childhood Impairments

At its previous meeting, the Advisory Group had considered an application for Section 60 support from the Oxford Register of Early Childhood Impairments (ORECI) [PIAG 4-09(b)/2003]. The application explained obtaining identifiable data with consent was impracticable because data on children with multiple impairments was collected from multiple contacts with the NHS; and because there was difficulty in diagnosing cerebral palsy (can take up to 5 years) – the applicant wished to avoid upsetting parents unnecessarily.

The application was approved subject to the following conditions being met by the applicant:

- That a system level security policy was provided and a risk assessment conducted for the Register;
- That information materials about the Register would be produced and distributed;
- That the Register implement its objectives on consent in a staged process over 24 months (Stage 1 within 12 months, Stages 2 and 3 within 24 months);
- That within 12 months the register develop a policy on data retention and destruction, with a view to removing identifiers from data as soon as practicable.

It was reported that the applicant had provided a system level security policy and had undertaken to meet the Advisory Group's other requirements. The Advisory Group was therefore content to formally approve the application.

ACTIONS: **(i) Secretariat to advise the applicant that their application for Section 60 support had been approved;**
(ii) Details of the application to be included in the Register of activities carried out with Section 60 support.

(ii) Application from Dr G W Odell (Guy's, King's and St Thomas' Dental Institute) for a "Ploidy" analysis study

At its previous meeting, the Advisory Group had considered an application from Dr G W Odell to process patient identifiable information for a "ploidy" analysis study [PIAG 4-09(f)/2003].

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

- That additional information be provided in order to demonstrate that an appropriate Information Custodian had been appointed for the study;
- That the applicant supply a detailed explanation of how the study will comply with each of the 8 principles of the Data Protection Act.

The Advisory Group was content with the response provided by the applicant and therefore formally approved the application.

ACTIONS: **(i) Secretariat to advise the applicant that their application for Section 60 support had been approved;**
(ii) Details of the application to be included in the Register of activities carried out with Section 60 support.

(ii) Application from Dr Jane Armitage (University of Oxford) for a study of cardiovascular events in diabetes (the "ASCEND" study)

At its previous meeting, the Advisory Group had considered an application from Dr Jane Armitage for Section 60 support to process patient identifiable information for a study of cardiovascular events in diabetes [PIAG 4-09(h)/2003].

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

- That the applicant confirm that initial contact with patients to obtain their consent will be via a clinician known to them (e.g. their GP or the consultant responsible for their care)
- That the applicant clarify what was meant by the "regulatory authorities" referred to in their consent form, and confirm that this form was approved by an appropriate research ethics committee
- That the applicant clarify their BS7799 status or advise when compliance was expected
- That the applicant provide a system level security policy and confirm when their corporate IT security policy was implemented
- That the applicant provide further information about their risk assessment – when was it undertaken, what did it recommend and when were the recommendations implemented?

The Advisory Group was content with the response provided by the applicant and therefore formally approved the application.

ACTIONS: **(i) Secretariat to advise the applicant that their application for Section 60 support had been approved;**
(ii) Details of the application to be included in the Register of activities carried out with Section 60 support.

(iii) Application from Dorset RDSU for a quantitative and qualitative evaluation of intermediate care of the elderly

At its previous meeting, the Advisory Group had considered an application from Dorset RDSU for Section 60 support to process patient identifiable information for an evaluation of intermediate care of the elderly PIAG 4-09(i)/2003].

The Advisory Group felt unable to approve the application because it was concerned that the reasons supplied by the applicant for not being able to obtain informed consent from patients were weak, and there was insufficient evidence to justify an assertion that "the numbers will be too large to make obtaining consent from each patient practical".

The Advisory Group considered the applicant's response but was not persuaded by the additional information it contained. It agreed that it would be inappropriate for the Advisory Group to approve the application because of funding issues. The Advisory Group also felt there was insufficient evidence to back up the applicant's claim that it would be impracticable to contact patients for consent as many would have moved - since the patient group involved was elderly and therefore traditionally less likely to move home. The application was therefore rejected.

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

(iv) Application from Professor Jenny Donovan (Department of Social Medicine, University of Bristol) for study to evaluate the effectiveness and cost-effectiveness of population based screening for prostate cancer

At its previous meeting the Advisory Group had considered an application for Section 60 support to process patient identifiable information for a study to evaluate the effectiveness of population based screening for prostate cancer [PIAG 4-09(k)/2003].

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

- That the applicant confirmed they would not include in the comparison arm of the study data about patients who opted out of the intervention arm;
- That the applicant conduct a formal risk assessment to inform the design of IT systems in advance of data collection, and provide information about the outcome of the assessment and any resulting actions required;
- That the applicant provide a system level IT security policy and commit to implementing it before data collection;
- That the applicant provide details of how they meet each of the 8 principles of the Data Protection Act.

The Advisory Group was content with the response provided by the applicant and therefore formally approved the application.

ACTIONS: (i) Secretariat to advise the applicant that their application for Section 60 support had been approved;
(ii) Details of the application to be included in the Register of activities carried out with Section 60 support.

(v) National Studies of Prison Suicides and Suicide in Recently Released Prisoners

At its previous meeting the Advisory Group had considered 2 applications for Section 60 support from the National Confidential Inquiry into Suicides and Homicides: (i) the National Study of Prison Suicides, and (ii) the National Study of Suicide in Recently Released Prisoners.

The Advisory Group agreed that the proposed studies were very important but it was concerned that Section 60 could not be used to allow access to prison health records, as it was uncertain whether or not the NHS was responsible for this data. It therefore asked that the applicants provide additional information and, if necessary, legal advice about who was responsible for the management of prison health data. In addition, the applicant was required to provide system level security policies for each study, and explain the arrangements for ensuring effective partition and separate processing of the data obtained for each study.

The Advisory Group was content with the applicant's response and therefore formally approved both applications.

ACTIONS: (i) Secretariat to advise the applicant that their applications for Section 60 support had been approved;
(ii) Details of the applications to be included in the Register of activities carried out with Section 60 support.

5. GMS/PMS Code of Practice on Confidentiality and Disclosure of Information

5.1. The Advisory Group received a presentation from Ms Donna Sidonio from the Department of Health on the Code of Practice for the GMS/PMS on Confidentiality and the Disclosure of Information [PIAG 1-04/2004].

5.2. Ms Sidonio explained that the Code of Practice described the circumstances in which patient data could be shared with PCTs and other organisations, but she sought comments from the Advisory Group on the document. Key issues identified by members were as follows:

- The Code required a strong introduction describing the legal framework around the use of confidential medical information
- The Code needed to provide clear definitions of who could access identifiable data and the circumstances in which they could access it

- The Code should emphasise that identifiable data would be accessed only in exceptional circumstances, and that PCTs would not ordinarily hold patient identifiable information
- The Code should clearly state that patient level data does not always have to be identifiable
- The Code required a glossary providing definitions of organisations and processes
- The Code should emphasise the need for an audit trail for reporting and reviewing when identifiable data had been used

5.3. Ms Sidonio agreed to incorporate the Advisory Group's comments into the Code and to circulate a further draft to members for comment.

ACTION: Ms Sidonio to revise the Code of Practice to take account of issues raised and to circulate a revised draft to members for further comment.

6. MRC Consultation on Consent and Confidentiality

6.1. The Advisory Group received a presentation from Peter Dukes and Philip Lord from MRC Management Group on the MRC's proposed consultation on consent and confidentiality. They received a number of comments from the Advisory Group as follows:

- It would be helpful if one of the end products of the project could be a document that mapped out a pathway that all research proposals should take
- Researchers needed to provide evidence that the validity of studies was undermined by patients failing to provide consent
- Researchers needed to justify all of the data items they collect – they should not process more information than was required for the purposes of their study
- Researchers need to build into their proposals the time and cost factors of obtaining patient consent
- It was important to establish an appropriate balance between the individual's right to privacy and the benefits of medical research
- Researchers must work within the law – the DPA, HRA, and the common law or Section 60
- It was important that policies should first of all aim to protect the relationship between patients and their doctors, and only then consider the interests of researchers
- Researchers need to establish appropriate arrangements for data archiving and destruction

6.2. Dr Dukes agreed to seek further involvement from some PIAG members at workshops planned as part of the consultation. He agreed to forward to the Secretariat details of any concerns that Researchers expressed about the Section 60 process.

ACTION: MRC to forward to PIAG Secretariat details of concerns about the Section 60 process arising from the consultation on confidentiality.

7. **NHS Care Records Service**

7.1 Discussion of the NHS Care Records Service was postponed because Mr Phil Walker was unable to attend the meeting. The Secretariat agreed to arrange a separate meeting to discuss the NCRS and the Advisory Group's future role in relation it.

7.2 In the meantime it was agreed that Ms Karen Thomson should attend, as an observer, meetings of the National Public Advisory Board on the Advisory Group's behalf.

ACTIONS: (i) Secretariat to arrange meeting to discuss NCRS in more detail.
(ii) Secretariat to inform NPfIT of Ms Thomson's attendance at NPAB meetings.

8. Applications for Section 60 Support

8.1 The Advisory Group considered new applications for Section 60 support as follows:

(i) Health Solutions Wales – National Community Child Health Dataset for Wales

8.2 The Advisory Group considered an application for Section 60 support from Health Solutions Wales [PIAG 1-07(b)/2004] to develop a National Community Child Health Dataset for Wales. The application explained that that the Child's and the Mother's NHS number were needed for linkage purposes. Consent was impracticable because database managers had no direct contact with patients and the database size is too large.

8.3 The Advisory Group noted that the application had been considered and rejected at the last meeting. Since then a number of fundamental changes have been made which represented a marked improvement:

- Information about the database would be made available to all new parents.
- An expert group, with patient representation was to be established.
- Postcode would not be collected centrally.
- NHS number would be collected centrally but will be held on a secure system – only anonymised information would be available for analysis.

8.4 The Advisory Group was therefore content to approve the application.

ACTIONS: (i) Secretariat to inform the applicant of the Advisory Group's approval.
(ii) Details of the application to be published in the Register of Activities carried out with Section 60 support.

ii) Application from the UK Renal Registry

8.5 The Advisory Group considered an application from the UK Renal Registry [PIAG 1-07(c)/2004] for Section 60 support for monitoring healthcare provisions to patients with renal conditions.

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

- The opt out option needs to be made clearer to the patients.
- To use only the minimum data that have been suggested to them.
- Need to be clearer on how long they retain the data for.
- Section 4 of their application needs to demonstrate a better understanding of the functions of Hospital Episode Statistics (HES) and the NHS Wide Clearing Service (NWCS).

ACTIONS: (i) Secretariat to inform the applicant of the Advisory Group's approval.
(ii) Details of the application to be published in the Register of Activities carried out with Section 60 support.

iii) British Regional Heart Study

8.7 The Advisory Group considered an application from the Royal Free and University College Medical School for Section 60 support for its British Regional Heart Survey [PIAG 1-07(d)/2004]. The study was to determine established and new risk factors responsible for variation in ischaemic heart disease and stroke (for men) in Great Britain. Section 60 support was required to trace 17% of patients who in 1978 consented to participate in the study but have been lost to contact.

8.8 The application was approved subject to the following conditions:

- The applicant should review their patient questionnaire and adapt it to make it clear that a patient's next of kin could not provide information on their behalf. Where a family member completed the questionnaire because the patient lacked capacity then this should be properly recorded.

ACTIONS: (i) Secretariat to inform the applicant of the Advisory Group's approval.
(ii) Details of the application to be published in the Register of Activities carried out with Section 60 support.

iv) University of Bristol – British Women's Heart and Health Study

8.9 The Advisory Group considered an application from the University of Bristol for its British Women's Heart and Health Study [PIAG 1-07(e)/2004]. The study aimed to determine established and new risk factors responsible for variation in ischaemic heart disease and stroke (for women) in Great Britain. Section 60 support was required to trace 11% of patients who in 1999 consented to participate in the study but had been lost to contact.

8.10 The application was approved subject to the following conditions:

- The applicant should review their patient questionnaire and adapt it to make it clear that a patient's next of kin could not provide information on their behalf.

Where a family member completed the questionnaire because the patient lacked capacity then this should be properly recorded.

ACTIONS: **(i) Secretariat to inform the applicant of the Advisory Group's approval.**
(ii) Details of the application to be published in the Register of Activities carried out with Section 60 support.

(v) British Association of Urological Surgeons – Registry of Urological Cancers (BAUS Cancer Registry)

8.11 The Advisory Group considered an application from the British Association of Urological Surgeons for a National Registry of newly diagnosed patients with urological tumours, used to analyse presenting features, the patient journey, and staging and treatment of patients [PIAG 1-07(f)/2004].

8.12 The application was rejected initially for the following reasons:

- The applicant need to demonstrate that it would be impracticable for them to obtain identifiable information with patient consent or to use psuedonymised data supplied by cancer registries.

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

(vi) Stockport Cardiovascular Disease Register

8.13 The Advisory Group considered an application from Stockport NHS Trust to pilot and establish a Stockport population-based CVD register, to support audit, patient safety and inform local health policy [PIAG 1-07(g)/2004]. Section 60 support was required for linkage and audit purposes.

8.14 This application was rejected for the following reasons:

- The applicant had not demonstrated that they had considered alternatives to processing identifiable data.
- It was recommended that the applicant consider using interrogation software to obtain anonymised data from GP systems, and it was suggested that they seek advice from Northumberland Care Trust where similar work has already been carried out.
- The applicant needed to do more to involve patient/user groups.

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

(vii) Manchester NHS Agency – Manchester Diabetes Electronic Record Service

8.15 The Advisory Group considered an application from Manchester NHS Agency for a register to track the clinical status and spread of CVD and diabetes in patients [PIAG 1-07(h)/2004]. It was claimed that Section 60 support was required due to the sheer numbers of patients at risk of CVD and diabetes.

8.16 The Advisory Group noted that the register held data on about 7,300 patients, who had provided consent to be registered. These patients represented about 48% of patients in the Manchester area with diabetes who attended hospital outpatient clinics. The Advisory Group felt that it would be wrong for the applicant to seek to collect data about patients who chose to receive all or the majority of their diabetes care in a primary care setting (the other 53%) without seeking their consent also.

8.17 In addition, the Advisory Group was concerned about proposals to register as many as an additional 200,000 patients who are at increased risk of diabetes or CVD. It was unclear from the application the basis for collecting data on approximately a third of the local population, whether it was likely that they had been advised by their GPs that they were considered to be at increased risk of DM/CVD, and what would be done to seek consent from patients after they had been registered.

8.18 The Advisory Group was of the view that the applicant should seek additional input from patients and user groups. It also recommended that the applicant seek advice from an ethics committee because of concerns that inclusion on the register – without a diagnosis - may have implications for patients (e.g. when seeking life or critical illness insurance).

8.19 The Advisory Group therefore did not approve the application.

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

(vii) London School of Economics – Study to explore socio-economic inequalities in access to diagnosis and treatment for colorectal cancer.

8.20 The Advisory Group considered an application from the London School of Economics for a study to explore socio-economic inequalities in access to diagnosis and treatment for colorectal cancer [PIAG 1-07(i)/2004]. Section 60 support was required because the applicant wish to obtain information from the Cancer Registries.

8.21 The application was approved subject to the following conditions

- Mr Donaldson would need to approve the proposed data storage.

8.22 The Secretariat was also asked to advise the applicant that they would need to improve patient /user involvement in the development of their work if they were to seek Section 60 support again.

ACTION: (i) Secretariat to confirm approval of the application as soon as appropriate security documentation had been obtained from the applicant.

(viii) Greater Manchester Ambulance Service Holistic Information Service

8.23 The Advisory Group considered an application from the Greater Manchester Ambulance Trust for its Ambulance Service Holistic Information Service [PIAG 1-07(j)/2004]. Section 60 support was required as it was claimed that it would be

impracticable to obtain consent from patients during ambulance call-outs due to the nature of the call and the priority of life saving.

8.24 The Advisory Group felt unable to approve the application at the current time. It was particularly concerned that there was not enough information on the application form to demonstrate how or why the applicant would use the data.

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

(ix) East Leeds PCT Regional Paediatric High Dependency Study Group – Study to determine the quantity and quality of paediatric high dependency care in the former Yorkshire region

8.25 The Advisory Group considered an application from East Leeds PCT for Section 60 support for a study to determine the quantity and quality of paediatric high dependency care in the former Yorkshire region [PIAG 1-07(k)/2004]. Section 60 support was required because of the large number of children involved and because their parents were not always available to provide consent.

8.26 The Advisory Group felt unable to approve the application at the current time for the following reasons:

- The applicant needed to explain why they needed to use all of the identifiable data items listed.
- The application needed to be reviewed by a MREC as it was a research proposal and not an audit exercise.
- Stronger evidence was required to explain why consent could not be obtained.

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

(x) Avon Health Protection Agency – System for routine surveillance of sexually transmitted diseases

8.27 The Advisory Group considered an application from Avon Health Protection Unit to establish a system for routine surveillance of sexually transmitted diseases [PIAG 1-07(l)/2004]. Section 60 support was required to process identifiable data in order that it could be anonymised but, due to the sensitive nature of STD information, few patients would provide consent.

8.28 The Advisory Group felt there was insufficient information to approve the application. The applicant was asked to provide additional information as follows:

- Evidence that they had involved patients and service users in the development of the study and that they had responded to any issues raised as concerns.
- That they undertake to use an encrypted Patient Identification number from each data source, or explain why this is impracticable.
- That they provide a clearer statement about how long they intended to retain patient identifiable information on their system.

- That they seek advice from the Department of Health's Sexual Health Data Group.
- That they provide a system level data security policy that explains:
    - System risk and security considerations
    - HPA security and confidentiality authority, accountabilities and delegations
    - Contractual/service level arrangements between the different organisations with which they were involved
    - Governing policy and standards

ACTION: Secretariat to obtain additional information from the applicant.

8.29 Northgate and Prudhoe NHS Trust – Study to find out how services respond to people with learning disability who commit offences

8.30 The Advisory Group considered an application from Northgate and Prudhoe NHS Trust for a study to find out how services respond to people with learning disabilities who commit offences [PIAG 1-07(m)/2004]. Section 60 support was required as it was claimed that only low levels of consent were likely to be obtained due to the client group, this would render the study unscientific.

8.31 The Advisory Group felt that there was insufficient information in the application to justify its approval. The applicant was asked to provide additional information as follows:

(i) Evidence that they have involved patients and service users in the development of the study and they had responded to any issues raised as concerns.
(ii) That they state how long it was intended to retain patient identifiable data and how they would effectively destroy data held electronically at the end of the retention period.
(iii) That they provide more information about how they will comply with the 8 data protection principles.
(iv) Since the Section 60 arrangements apply in England and Wales only, they would need to provide evidence that they conformed with arrangements in place in Scotland for any data collected in relation to patients who receive treatment there.
(v) That they explain how they propose to anonymise information before it is loaded on to the laptops to be used for study purposes.
(vi) That they inform their MREC that they would process patient identifiable information with Section 60 support rather than informed consent.

ACTION: Secretariat to obtain additional information from the applicant.

(xi) National Cancer Services Analysis Team – Collation and analysis of data regarding patients receiving chemotherapy

8.32 The Advisory Group considered an application from the National Cancer Services Analysis Team for its collation and analysis of data regarding patients receiving chemotherapy [PIAG 1-07(n)/2004]. Section 60 support was required as data is required from Hospital Episode statistics and cancer registries that do not have direct contact with patients to obtain consent.

8.33 The Advisory Group felt unable to approve the application. The applicant was required to consider the following issues:

- How to involve patients in this work, and demonstrate their views were taken into account when developing safeguards or patient information materials.
- How to provide greater clarity about the proposed purpose of work in this area, and more information about why obtaining informed consent or using anonymised data are not practicable alternatives.

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

(xii) National Cancer Services Analysis Team – Analysis of attendance at hospitals in the Cheshire and Merseyside Strategic Health Authority

8.34 The Advisory Group considered an application from the National Cancer Services Team for its analysis of attendance at hospitals in the Cheshire and Merseyside Strategic Health Authority. The study had particular reference to geographic catchment areas and the implication on patient travel times of proposed service reconfiguration, and variations in uptake of service compared to deprivation index [PIAG 1-07(o)/2004]. Section 60 approval was required as consent could not be gained as the data are been given to the team retrospectively and some of the patients involved may be deceased.

8.35 The Advisory Group was content to approve the application.

ACTIONS: (i) Secretariat to inform the applicant of the Advisory Group's approval.
(ii) Details of the application to be published in the Register of Activities carried out with Section 60 support.

(xiii) National Cancer Services Analysis Team – Collaboration with cancer registries to merge data

8.36 The advisory Group considered an application from the National Cancer Services Analysis Team to merge data held by the applicant with data held by cancer registries in order to provide a stronger database [PIAG 1-07(p)/2004]. Section 60 support was required as the applicant has no link with patients and receives its data from organisations that have no direct relationship with patients.

8.37 The Advisory Group was content to approve the application.

ACTIONS: (i) Secretariat to inform the applicant of the Advisory Group's approval.
(ii) Details of the application to be published in the Register of Activities carried out with Section 60 support.

(xiv) UK National Barrett's Oesophagus Registry

8.38 The Advisory Group considered an application from the UK National Barrett's Oesophagus Foundation and Royal Free Hospital NHS Trust to maintain a register of patients with Barrett's Oesophagus who are at increased risk of cancer. It was claimed that Section 60 support was required as it was inappropriate to obtain consent from patients prior to endoscopy as only 5% of patients would have Barrett's Oesophagus.

8.39 The Advisory Group felt that they were unable to approve the application. More information was required from the applicant to establish why they were not able to gain consent when the patient was attending their outpatient appointment.

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

9. Any Other Business

9.1 There was no other business.

10. Date of Next Meeting

10.1 Future meetings of the Advisory Group have been scheduled as follows:

- Monday 7 June 2004
- Monday 13 September 2004
- Monday 6-7 December 2004