PATIENT INFORMATION ADVISORY GROUP

Meeting on Monday 7 June 2004

Minutes

1. Present

Members: Professor Joan Higgins (Chair), Professor Michael Catchpole, Professor Sir Cyril Chantler, Dr Tricia Cresswell, Mrs Helen Darracott, Mr Micheal Hake, Ms Barbara Meredith, Professor Sir Denis Periera Gray, Mrs Shahwar Sadeque and Ms Karen Thomson.

In attendance: Mr Sean Kirwan and Miss Victoria Lowther

2. Apologies

2.1 Apologies were received from: Mr Patrick Coyle, Ms Helen Miller, Ms Julia Palca and Dr Michael Wilks.

3. Minutes of last meeting

3.1 The Minutes of the previous meeting of the Advisory Group that had taken place on 2 March 2004 [PIAG 2-02/2004] were agreed to be a true record.

4. Matters arising/action points

Letter from Leeds Teaching Hospitals NHS Trust

4.1 The Advisory Group considered a letter received by the Secretariat from a member of staff at Leeds Teaching Hospitals NHS Trust. The letter raised concerns about an 'extensive range of patient identifiable information being held and used without consent' across a number of databases, and an increasing capability for a small group of clinicians to 'crosscheck and combine' databases. The Advisory Group was asked to consider what steps, if any, should be taken by the Secretariat to respond to the letter. The following actions were agreed:

- For Professor Higgins to write to the Caldicott Guardian at Leeds Teaching Hospitals NHS Trust to explain that representatives from the Advisory Group wish to meet to discuss arrangements relating to their section 60 support.
- That the Secretariat should arrange an inspection of databases housed by Leeds Teaching Hospitals NHS Trust with Section 60 support, and to report the outcome to a future meeting of the Advisory Group.

ACTION: **(i) Chair to write letter to Caldicott Guardian of Leeds Teaching Hospitals NHS Trust.**
(ii) Secretariat to review security and confidentiality arrangements of databases associated with Leeds Teaching Hospitals NHS Trust, and to report outcome to the Advisory Group.

Clinical Audit

4.2 Mr Kirwan reported that the Secretariat had received several representations from clinicians in relation to the principles established by the Advisory Group on the circumstances in which Section 60 support should be sought for clinical audit. The Advisory Group was asked to confirm whether it was still content with the following concerning clinical audit:

- Organisations did not need to apply for Section 60 Support for clinical audit where patient identifiable information would be seen only by staff employed by the NHS organisation that provided their treatment.
- In the absence of informed consent, Section 60 support should be sought where patient identifiable information crossed organisational boundaries (eg regional or national audits).

4.3 Mr Kirwan confirmed that strict adherence to these principles had caused some frustration for clinicians where patients received treatment for a single disease or condition from more than one NHS organisation (e.g. cancer networks and Ambulance Trusts) because they were unable to obtain data from other each organisation in order to build up a full picture of the care episode for clinical audit purposes.

4.4 The Advisory Group agreed that it was content for patient identifiable information to be processed across organisational boundaries for clinical audit purposes where the following criteria were met:

- The data relates to a single episode of care, or the treatment of a particular disease or condition,
- the data was being processed by staff employed by the NHS organisations that have provided that care or treatment
- The exercise had been approved by the Medical Director of the trust involved and the use of patient information approved by the Caldicott Guardian.

ACTION: Secretariat to revise Section 60 guidance on clinical audit.

Previous Applications for Section 60 Support

4.5 At its previous meetings the Advisory Group requested that additional information be provided before the applications could be approved, as follows:

(i) Application from Avon Health Protection Unit

At its previous meeting the Advisory Group had considered an application for Section 60 support from the Avon Health Protection Unit to establish a system for routine surveillance of sexually transmitted diseases [PIAG 1-07(l)/2004]. The application explained that obtaining patient consent to use identifiable information was not practicable because of the sensitive nature of STD data means that few patients would be willing to consent and because the applicant ultimately wished to process anoymised information.

The applicant was informed that the Advisory Group would not be able to approve the application until the following information had been provided:

- That they provide evidence that they had involved patient and service users in the development of the study and demonstrate that they had responded to any issues raised as concerns.
- That steps be taken to encrypt the Patient Identification number from each data source, or explain why it was 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 explained:
    - System risk and security considerations
    - HPA security and confidentiality authority, accountabilities and delegations
    - Contractual/service level arrangements between the different organisation with which you are involved
    - Governing policy and standards

The Advisory Group considered a submission by the applicant that addressed each of these concerns, and agreed that they had been adequately addressed. The Advisory Group was therefore content to formally approve the application.

ACTIONS: (i) Applicant to be informed of the Advisory Group's decision.

(ii) Details of the application to be published on the Register of activities carried out with Section 60 support.

(ii) Northgate and Prudhoe NHS Trust – Study to find out how services respond to people with learning disabilities who commit offences

At its previous meeting the Advisory Group had 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, and this would render the study unscientific.

At that time the Advisory Group had felt that there was insufficient information in the application to justify its approval. 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 they had responded to any issues raised as concerns.
- That they state how long they intended to retain patient identifiable data and how they would effectively destroy data held electronically at the end of the retention period.
- That they provide more information about how they would comply with the 8 data protection principles.
- 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.
- That they explain how they propose to anonymise information before it is loaded on to the laptops to be used for study purposes.
- That they inform their MREC that they would process patient identifiable information with Section 60 support rather than informed consent.

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

ACTION: (i) Applicant to be informed of the Advisory Group's decision.
(ii) Details of the application to be published on the Register of activities carried out with Section 60 support.

(iii) Application from the National Cancer Services Analysis Team for National Chemotherapy Dataset project

At its previous meeting the Advisory Group had considered an application from Helen Forbes at the National Cancer Analysis Team to process patient identifiable information for a National Chemotherapy Dataset Project [PIAG 1-07(n)/2004]. The application explained that obtaining patients consent was impracticable because the data would be obtained from organisations that do not have direct contact with patients.

The Advisory Group had felt unable to approve the application and recommended that the Applicant should do more to involve patients in this work, and demonstrate that they have taken account of their views in developing safeguards and producing patient information materials. In addition, the Advisory Group sought greater clarity about the proposed purpose of the work in this area and more information about why obtaining informed consent or using anonymised data are not practicable alternatives.

The Advisory Group was content with the additional information provided in response by the applicant and was content to formally approve the application.

ACTION: **(i) Secretariat to inform the applicant of the Advisory Group's decision.**
(ii) Details of the application to be published on the Register of activities carried out with Section 60 support.

Report on the meeting on 28 April to discuss the NHS Care Record Service [PIAG 2-03(a)/2004]

4.6 The Advisory Group considered a draft report of a special meeting that had taken place on the 28 April to discuss the NHS Care Records Service [PIAG 2-03(a)/2004]. Those who attended the meeting agreed it to be an accurate record subject to one minor amendment, which was incorporated into the final document.

5. Healthcare Commission Draft Code of Practice on Access to Personal Information

5.1 The Advisory Group considered a press release and accompanying consultation document from the Healthcare Commission on their draft code of practice on access to personal information [PIAG 2-04/2004]. The draft code explained how the Healthcare Commission intended to obtain and use personal information, which identifies patients, staff and others. The Advisory Group had considered an earlier draft of this document at its previous meeting on 2 March, and agreed that the Commission would play an essential role in

improving the provision of healthcare by the NHS and although it had no interest in obstructing the Healthcare Commission's work, it wished to ensure that it employed and promoted best practice.

5.2 The Advisory Group identified the following issues to be highlighted in its response to the consultation:

- Under *Working with other bodies* the Commission should provide specific examples of the organisations and circumstances in which it will need to develop arrangements for effective co-ordination (para 8, 2nd bullet point)
- Under *Obtaining access to personal information – when obtaining personal information without consent may be justified* the Commission needs to identify specific circumstance in which patient identifiable information is required and where it is unlikely that obtaining consent will ever be practicable, and press the Government to introduce new legislation that will allow data to be processed securely (para 16)
- The Commission needs to explain who will be responsible for obtaining informed consent from patients for their data to be used/shared by the Commission(para 27).
- In relation to patients from ethnic minority groups, the Commission should explain who would be responsible for providing information materials and ensuring that interpreters are properly trained.
- The commitment to maintaining an audit trail of the circumstances in which the Commission has processed identifiable patient information even though patients have withheld consent is commendable. However, the reasons for overriding patients consent should be made publicly available (paras 33-36)
- The Commission should be taking steps to improve the use of the NHS number by NHS organisations. Ultimately the Commission should aim to use the NHS number as the sole patient identifier for linkage and other purposes.
- The Commission should only share identifiable information with third parties after informed consent has been obtained from patients (para 50).
- The Commission needs to ensure that the annual review of the Code of Practice is properly independent. It should consider seeking input from PIAG into this process.

5.3 Members were invited to submit further comments on the draft Code of Practice to the Secretariat by the end of June.

ACTIONS: (i) Members to forward additional comments to the Secretariat.
(ii) Secretariat to respond to the consultation on the Advisory Group's behalf.

6. Annual review of Section 60 Regulations

6.1 The Advisory Group considered a paper on the 2004 annual review of regulations made under Section 60 [PIAG 2-05/2004]. Submissions from the United Kingdom of Cancer Registries (UKACR) and the Health Protection Agency (HPA). The regulations fell into two categories, specific support and class support.

Submission by Cancer Registries

6.2 The Advisory Group welcomed the work that had been undertaken during the previous year and considered the submission from the UKACR describing the steps taken by cancer registries to improve the way they processed patient identifiable information.

6.3 The UKACR had produced a second version of their policy on data retention and disposal to address concerns from the Advisory Group that cancer registries should comply with patient requests to delete their records. The Advisory Group approved the revised policy.

6.4 The Advisory Group considered Annex D of the UKACR submission, which attempted to clarify the definition of identifiable information. This was in light of guidance from the Office for National Statistics, which recommended that for tabulated data, any cell count of less than 5 should be suppressed in any geographical unit less that an entire country. The Advisory Group agreed that agreed that sometimes it was necessary to include cell counts of less than five at PCT level in order to support the commissioning of services. Members agreed that the it would be appropriate for the registries to judge on a case by case basis whether it was appropriate to use provide tabulated data with cell counts less than 5 to NHS organisations.

6.5 The Advisory Group recommended that the UKACR should be required to undertake additional work as follows during the next 6 months:

- That the UKACR develop a communications strategy for patients from ethnic minority groups. Information leaflets should be culturally relevant to the specific groups and not simply translated from the English language version, and consideration should be given to making information available in a range of media (e.g. audio tapes).
- That the patient information leaflet needed to advise patients that they had a right to object to cancer registries holding information about them.
- The UKACR needed to submit within 6 months a strategy framework document for change, which details specifically when cancer registries would be able to resort to use of the NHS Number as the sole patient identifier.

Submission by the Health Protection Agency

6.6 The Advisory Group welcomed the work that had been undertaken during the previous year and agreed that the HPA response was particularly positive.

6.7 The submission detailed in particular that the HPA had undergone extensive organisational change with many of the Public Health Laboratories having moved to the NHS with the data handling/data collection and Caldicott/data protection compliance being part of the NHS Trust Hospitals of which they are now a part.

6.8 The HPA asked specifically if it was able to retain the full postcode for re-mapping historical trends. The Advisory Group agreed that they should be able to continue this work, but that ultimately postcodes should be pseudonymised. Members asked that the Secretariat find out if and when the National Programme for IT will be able to provide a postcode mapping service.

6.9 The Advisory Group confirmed that it was content for the HPA to process patient identifiable information in relation to its work on monitoring chemical hazards and poisons.

6.10 The Advisory Group asked that the HPA provide clarification on the following issues:

- That the HPA provide information about how they meet principle 7 of the Data Protection Act 1998.
- To provide information on whether patients are able to opt-out of having their identifiable information processed.
- That in future years the National Public Health Service of Wales should make a submission with the HPA covering improvements in Wales.

Class Support Regulations

6.11 The Advisory Group had previously agreed that each activity carried out under the class support arrangements should be reviewed on the anniversary of the original application receiving PIAG approval. The Secretariat would then use these reports to compile a single annual submission to PIAG on progress made by the organisations.

6.12 The Secretariat reported to members that they were still waiting to hear from two applicants out of thirty. The Secretariat also reported that, on a whole, the responses received where very positive and addressed all of the conditions set out by the Advisory Group. These details would be fed into the Register of approved applications on the Advisory Group's website in due course.

6.13 However, it was agreed that the Secretariat should indicate to several organisations that they needed to make more effort towards moving towards using the NHS number as the sole patient identifier processed.

6.14 In particular, the Advisory Group was disappointed that the Healthcare Commission's submission in respect of the Section 60 support granted to the National Clinical Audit Support Programme did not place sufficient emphasis on use of NHS number as a patient identifier. The Advisory Group believed that the Commission was uniquely placed to pressure NHS organisations to make improvements in this area, and that it should consider setting targets in order to increase the use of the NHS number.

ACTIONS: (i) Secretariat to inform organisations of the outcome of their annual reviews.

7. NHS Care Records Service

7.1 The Advisory Group received a presentation from Ms Julie Clifton, Head of Stakeholder Engagement at the National Programme for IT (NPfIT). Ms Clifton updated Members on NPfIT progress as follows:

- Procurement exercise had been successfully completed;
- The National Programme had moved into implementation phase, headed by Professor Aidan Halligan;
- The next stage of stakeholder engagement and communications was being planned – 428 stakeholders across 32 different groups had been identified.

7.2 The Advisory Group identified the following issues and concerns it had in relation to stakeholder involvement:

- The content of each patient record should be agreed with the patient. This would require consent to be built properly into the system and for clinicians to check with patients for each healthcare episode
- The NHS number needed to be used across the NCRS, and there needed to be a distinction between NHS and Social Services organisations in terms of who could access data
- NHS staff needed to interact effectively with the new systems and this would require adequate resources for training
- Communications needed to focus on informing patients that they have control over the content of their records and the steps they could take to have more influence on who had access to them

7.3 The Advisory Group also emphasised the importance of ensuring that the communications campaign was a 2-way process – enabling patients and other stakeholders to effectively feed in change.

7.4 The Advisory Group remained concerned that the National Programme had failed to confirm that patients would be entitled to withhold data from the NCRS "spine". It therefore agreed to invite Professor Halligan to attend a future meeting to discuss this issue.

ACTION: Chair to write to Professor Halligan, setting out the Advisory Group's concerns and inviting him to discuss them at a future meeting.

8. New Applications for Section 60 Support

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

(i) University of Oxford - the Oxford Monitoring System for Attempted Suicide [PIAG 2-07(b)/2004]

8.2 The Advisory Group considered an application for Section 60 support from the Oxford Monitoring System for Attempted Suicide for a register on all deliberate self-harm presentations to the general hospital in Oxford. The applicant claimed that obtaining consent was impracticable because it needed to be gained while patients were in A&E and were therefore available only for short periods of time; the sensitive nature of self harm patients information; and due to the capacity of patient to give informed consent following deliberate self harm.

8.3 The application was approved subject to the applicant meeting the following conditions:

- Extension of the dataset to include the NHS number within six months,
- To develop an exit strategy from Section 60 by moving towards using the NHS number as sole patient identifier within 12 months,
- To amend the patient information leaflet so that it included more details about the register.

ACTION: **(i) Secretariat to inform the applicant of the Advisory Group's decision.**
(ii) Details of the application to be published on the Register of activities carried out with Section 60 support.

(ii) University of Manchester - the Manchester Self Harm Project [PIAG 2-07 (c)/2004]

8.4 The Advisory Group considered an application from the Manchester Self-Harm Project at the University of Manchester for Section 6 support for a monitoring scheme of deliberate self-harm. Consent was impracticable because: the size of the database which holds information on 12,000 patients; failure to consent would adversely effect the results of the study; asking for consent would increase the burden on NHS staff.

8.5 The application was approved subject to the following conditions:

- That the applicant makes efforts to seek patient input on the scheme,
- To develop an exit strategy from Section 60 support by moving towards using the NHS number as sole patient identifier within 12 months,

ACTION: **(i) Secretariat to inform the applicant of the Advisory Group's decision.**
(ii) Details of the application to be published on the Register of activities carried out with Section 60 support.

(iii) University of Leeds – A Research monitoring system of hospital attendance due to self harm [PIAG 2-07(d)/2004]

8.6 The Advisory Group considered an application from Leeds University for Section 60 support for a monitoring system of deliberate self-harm. The applicant

argued that obtaining patient consent was impracticable because this may cause patients distress; more than 2000 patients a year could be identified; and it was impracticable for A&E staff to obtain consent.

8.7 The application was approved subject to the following conditions:

- That the applicant reviews whether they need all the items in the large dataset.
- That the applicant reassures the Advisory Group that they will not pass identifiable information onto third parties.

ACTION: (i) Secretariat to inform the applicant of the Advisory Group's decision.
(ii) Details of the application to be published on the Register of activities carried out with Section 60 support.

(iv) Stockport NHS Trust – Stockport population based cardio-vascular diseases (CVD) register [PIAG 2-07(e)/2004]

8.8 The Advisory Group considered an application from Stockport NHS Trust for Section 60 support to pilot and establish a Stockport population-based CVD register, to support audit, patient safety and inform local health policy. The applicant argued that obtaining consent was impracticable for the project because failure to recruit all patients would undermine the effectiveness of the register.

8.9 The Advisory Group noted that the application had been considered and rejected at its previous meeting. However, since then the applicant had consulted with patients, investigated the feasibility of using interrogation software and provided stronger evidence to justify the use of identifiable information without consent. The application was therefore approved subject to the following conditions:

- That the applicant develop an exit strategy by aiming to anonymise patient information,
- That the applicants commit to work more closely with patients,
- That the patient information leaflet include a telephone number for patients who may not speak English.

ACTION: (i) Secretariat to inform the applicant of the Advisory Group's decision.
(ii) Details of the application to be published on the Register of activities carried out with Section 60 support.

(v) University of Leeds – the Yorkshire Register of Diabetes in Children and Young People [PIAG 2-07(f)/2004]

8.10 The Advisory Group considered an application from the University of Leeds for Section 60 support for a register of diabetes in Children and Young People for auditing patient care and for conducing epidemiological analyses. The applicant argued that it was not practicable to obtain consent for more than 50% of the children and young people diagnosed annually with diabetes in Yorkshire – mainly for those

aged 15 years or over.

8.11 The Advisory Group felt unable to approve that application for the following reasons:

- It believed it would be practicable for the applicant to obtain patient consent given that the patients had frequent contact with health professionals.
- Alternatively, the applicant needed to develop a strategy to use NHS number as the sole patient identifier for record linkage.

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

(vi) British Association of Urological Surgeons – registry of Urological Cancers (BAUS Cancer registry) [PIAG 2-07(g)/2004]

8.12 The Advisory Group considered an application from the British Association of Urological Surgeons (BAUS) for Section 60 support for a register of patients with urological cancer to monitor and improve patient care. Section 60 support was required while the applicant developed a strategy to use pseudonimised information.

8.13 The application was approved subject to the following conditions:

- That patient identifiable information should be securely held at BAUS headquarters rather than at the home of a BAUS employee

ACTION: (i) Secretariat to inform the applicant of the Advisory Group's decision.
(ii) Details of the application to be published on the Register of activities carried out with Section 60 support.

(vii) University of Leeds – Study on the epidemiology of conversion disorders [PIAG 2-07(h)/2004]

8.14 The Advisory Group considered an application from the University of Leeds, for a study to identify and monitor new cases of apparent neurological disorders in secondary care services in Leeds, which are found to have no medical explanation (conversion disorders). The applicant argued that obtaining patient consent was impracticable due to: there being a large number of patients involved; gaining consent would not be relevant from the majority of A&E patients; failure to obtain consent would adversely affect the study; and there was no clear coding system available to select the patients needed for the study anonymously.

8.15 The Advisory Group felt unable to approve the application for the following reasons:

- The reasons provided for not obtaining patient consent were weak,
- A fuller explanation was required about why using anonymised information was not an appropriate alternative,
- A clearer definition of the patients covered by the study was required so that issues around the use of the NHS number can be better understood,

- It was unclear why the study was seeking to identify patients from A&E records rather than GP practice records.

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

(viii) The Royal College of Surgeons – study to determine whether HES data linked with ONS mortality data can be used to audit surgical procedures [PIAG 2-07(I)/2004]

8.16 The Advisory Group considered an application from the Royal College of Surgeons of England for Section 60 support to audit the outcome after surgical procedure using linked HES and ONS mortality data. The applicant argued that Section 60 support was required because the cohort study was too large to obtain consent and the applicant did not have addresses to contact patients.

8.17 The Advisory Group noted that the applicant would only receive identifiable information relating to deceased patients. It was therefore content to approve the application. However, the Advisory Group requested that the applicant should amend their protocols to ensure that a patient's relatives could only access information about them with their consent.

ACTION: (i) Secretariat to inform the applicant of the Advisory Group's decision.
(ii) Details of the application to be published on the Register of activities carried out with Section 60 support.

(ix) Croydon Primary Care Trust – the South West London and Surrey & Sussex Regional Perinatal audit/birth survey [PIAG 2-07(j)/2004].

8.18 The Advisory Group considered an application from Croydon Primary Care Trust for Section 60 support to audit a database of information about all mothers and babies in South West London and Surrey and Sussex, to identify and explain variations in death rates, maternity and neonatal services and monitor these over time. The applicant argued that obtaining patient consent for the project would be impracticable as the database held information on approximately 30,500 patients and this would mean obtaining consent prospectively from parents with babies in intensive care. Parents were informed at the time as to the use of information to be held on the database.

8.19 The application was approved subject to the following conditions:

- That the applicant make a commitment to use the NHS number as the sole identifier for the database and the audit by January 2005.

ACTION: (i) Secretariat to inform the applicant of the Advisory Group's decision.
(ii) Details of the application to be published on the Register of activities carried out with Section 60 support.

(x) Mrs Julietta Patnick – Study to examine a possible "halo" effect of Colorectal Cancer Screening [PIAG 2-07(k)/2004]

8.20 The Advisory Group considered an application from the NHS Cancer Screening Programme for Section 60 support for a study to examine a possible "halo" effect of colorectal cancer screening. The study was based on an assumption that screening service may influence health behaviour in target and non-target populations. The applicant argued that obtaining patient consent was impracticable as there were over 180,000 patients invited for colorectal screening and a large number of patients in West Midlands were diagnosed with symptomatic colorectal cancer in 2000-2002.

8.21 The application was approved subject to the applicant improving their patient involvement in the study.

ACTION: (i) Secretariat to inform the applicant of the Advisory Group's decision.
(ii) Details of the application to be published on the Register of activities carried out with Section 60 support.

(xi) Professor Julia Newton Bishop – Studies of familial melanoma [PIAG 2-07(l)/2004)

8.22 The Advisory Group considered an application form Cancer Research UK Clinical Centre for Section 60 support for a study to identify genes, which predispose to melanoma and to determine how these genes interact with each other and with the environment. The applicant sought approval for this study and then to carry on using identifiable information and to re-contact patients.

8.23 The application was approved subject to the following conditions:

- That the applicant confirm the time-scale for the destruction of data.
- That the applicant addresses issues arising from the Data Protection Act regarding information about family history.

ACTION: (i) Secretariat to inform the applicant of the Advisory Group's decision.
(ii) Details of the application to be published on the Register of activities carried out with Section 60 support.

(xi) Kay Rushforth – study to determine the quantity and quality of Paediatric High Dependency Care in the former Yorkshire region [PIAG 2-07(m)/2004].

8.24 The Advisory Group considered an application from East Leeds Primary Care Trust for Section 60 support for a study to determine the quantity and quality of Paediatric high dependency care in the former Yorkshire region. The applicant argued that obtaining patient consent was not practicable due to the large numbers of patients involved, because the parents of patients are not always available and because gaining consent is not always be a priority for NHS staff.

8.25 The application was approved subject to the following conditions.

- That the applicants make a commitment to using the NHS Number as the primary identifier in the study and that they inform the Advisory Group of the timescales for achieving this goal.
- That the applicant ensure that all parents of patients receive the information leaflet.

ACTION: **(i) Secretariat to inform the applicant of the Advisory Group's decision.**
(ii) Details of the application to be published on the Register of activities carried out with Section 60 support.

(xii) Oxford Vaccine Group – A Phase II, Randomised, Open Label, Controlled, Multicentre Study to evaluate Safety, Immunogenicity and Induction of Immuniological Memory after Two or Three doses of a Menongococcal ACWY Conjugate Vaccine Administered to Health infants at 2, 3, 4 Months of Age [PIAG 2-07(n)/2004]

8.26 The Advisory Group considered an application for Section 60 support for a study to evaluate the safety after administration of the new Menongococcal ACWY vaccine to healthy infants 2, 3 and 4 months of age. The applicant argued that obtaining parental consent was not practicable, as approaching parents at first immunisation would not give the applicant enough time to consider the details.

8.27 The Advisory Group was unable to approve the application because the applicant proposed to recruit patients by contacting their parents directly, contrary to the principle established by the Group patients should only be contacted by clinicians with whom they had established a relationship.

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

(xiii) National Heart and Lung Institute, Imperial College – Environmental Monitoring of an Integrated Transport Strategy: a case referent analysis [PIAG 2-07(o)/2004]

8.28 The Advisory Group considered an application from the National Heart and Lung Institute for Section 60 support for a study into public health effects of a new transport strategy in Oxford. Section 60 support was required as the study team needed to undertake local analyses using full postcode.

8.29 The Advisory Group approved the application.

ACTION: **(i) Secretariat to inform the applicant of the Advisory Group's decision.**
(ii) Details of the application to be published on the Register of activities carried out with Section 60 support.

(xiv) Small Area Health Statistics Unit, Imperial College – Study to determine if there is a relationship between chlorination disinfection by-products in drinking water and the risk of congenital anomalies in the UK [PIAG 2-07(p)/2004].

8.30 The Advisory Group considered an application from the Small Area Health Statistics Unit at the Imperial College London for Section 60 support for a study to determine if there is a relationship between chlorinated disinfecting by-products in drinking water and the risk of congenital anomalies in the UK. The applicant argued that obtaining patient consent was impracticable due to the size of the study, which would include data on 75,000 patients collected retrospectively.

8.31 The application was approved subject to the study using the mother's age and not the date of birth.

ACTION: (i) Secretariat to inform the applicant of the Advisory Group's decision.
(ii) Details of the application to be published on the Register of activities carried out with Section 60 support.

(xv) National Cancer Services Analysis Team – Analysis of attendance at hospitals in the Cheshire and Merseyside Strategic Health Authority, with particular reference to geographic catchment areas and the implementation on patient travel times of proposed service reconfiguration, and variations in uptake of service compared to deprivation index [PIAG 2-07(q)/2004].

8.32 The Advisory Group considered an application from the National Cancer Service Analysis Team for Section 60 support for an analysis of attendances at hospitals, GP surgeries and emergency ambulance journeys in the Cheshire and Merseyside Strategic Health Authority. The study would make particular reference to geographical catchment area, and the implication on patient travel times of proposed service reconfiguration and variations in uptake of services compared to deprivation index. The application was an extension of a previous application to include data from GP surgeries and emergency ambulance journeys. The applicant argued that consent was not practicable because data was obtained from a pre-existing source and given to applicants retrospectively.

8.33 The Advisory Group approved the application.

ACTION: (i) Secretariat to inform the applicant of the Advisory Group's decision.
(ii) Details of the application to be published on the Register of activities carried out with Section 60 support.

(xvi) National Cancer Services Analysis Team – Collation and analysis of data regarding patients receiving palliative care in the UK [PIAG 2-07(r)/2004]

8.35 The Advisory Group considered an additional application from the National Cancer Services Analysis Team for Section 60 support for the collation and analysis of data regarding patients receiving palliative care in the UK. The application argued that obtain patient consent was not practicable as the data would be obtained from

pre-existing sources, and the information was about the terminally ill and therefore it was anticipated that a significant number would have died or have been close to death.

8.36 The Advisory Group was content to approve the application.

ACTION: **(i) Secretariat to inform the applicant of the Advisory Group's decision.**
(ii) Details of the application to be published on the Register of activities carried out with Section 60 support.

9. Any Other Business

9.1 Mr Kirwan agreed to send a note to members of the Advisory Group explaining why the new GMS contract meant that the regulations made under Section 60 of the Health and Social Care Act 2001 no longer needed to be revised.

10. Date of next meeting

10.1 Future meetings of the Advisory Group were scheduled as follows:

- Monday 13 September 2004
- Monday 6 December 2004