

Meeting held on Wednesday 13 December 2006 at 9.30am

Present:

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

In attendance: Dr Patrick Coyle (SCAG), Ms Diana Kerrigan (Secretariat), Ms Melanie Kingston (Secretariat), Mr Sean Kirwan (DHIPU), Professor Martin Severs, (ISB) and Ms Karen Thomson (Secretariat)

1. Welcome and Apologies for absence

1.1 Apologies were received from Dr Tricia Cresswell and Dr Fiona Douglas.

2. Minutes of last meeting

2.1 Minutes of the previous meeting held on Monday 11 September 2006 were agreed to be an accurate record.

3. Matters Arising/Action Points

3.1 The Chair reported that both she and Ms Ellis had attended the recent UK Caldicott Guardians Council (UKCGC) meeting. It was noted that Ms Ellis would be attending every meeting representing the Advisory Group, and that the Chair would also attend when she could.

3.2 The Chair reported that no response had been received from the speakers at the AMS Symposium. Similarly, no response had yet been received from Sir Ian Kennedy or Ms Anna Walker at the Healthcare Commission. It was reported that this was being taken seriously by the Commission and that a response would be forthcoming.

Action – Secretariat to follow up with the Commission

3.3. The Chair reported that a response from David Nicholson had just been received in relation to consent for disease registers. It was agreed that this should be followed up with Mr Phil Walker.

Action – Secretariat to follow up with Mr Walker

4. Secretariat Report

4.1 The Secretariat report was received and its contents noted.

4.2 Consolidation of legislation

It was noted that the NHS Act 2006 had consolidated health legislation. Under the new Act, which received royal assent in November 2006, Sections 60 and 61 of the Health and Social Care Act 2001 had become Sections 251 and 252. Consideration would be given to how best to update documents and utilise the new designated legislative reference.

[Note from the Secretariat: It would appear that that there is no requirement to change the legislative reference following consolidation. Consequently, it is proposed to continue to refer to S60 and S61 but adding a footnote to new and revised documents, to refer to the consolidation Act where appropriate.]

4.4 Human Fertilisation and Embryology Authority

The Secretariat had met with DH staff responsible for the Human Fertilisation and Embryology Authority (HFEA) to discuss plans for the proposed merger of the HFEA and Human Tissue Authority. The new body will be known as Regulatory Authority for Tissue and Embryos (RATE). As part of the legislative requirements for this, there were proposals to include significant changes with respect to researchers' access to data held in the HFEA register.

A number of issues were discussed, both with respect to prospective consent by birth parents for data to be used for research and dealing with disclosure of retrospectively held data. It was agreed that the Secretariat should seek a meeting with the HFEA to explore further possible solutions to the confidentiality issues this has raised and to highlight the activities that could be facilitated through Section 60¹ approval.

Action: Secretariat to seek meeting with the HFEA

4.3 GP Patient Experience Survey

The Chair welcomed Mr Richard Armstrong, Head of Primary Medical Care for the Department of Health to discuss the GP Patient Experience Survey (previously referred to as the National Patient Experience Survey).

Mr Armstrong began by apologising for not having consulted formally with the Advisory Group before now. This was in part due to the timing of meetings but also because of discussions with the GP Committee of the BMA. He provided an overview of the proposed survey and how it had changed from being about both access and choice to focussing just on questions relating to access to GP services. He also explained why the Apollo system had been chosen in preference to the Exeter system (NHAIS), for extraction of patient details. Namely, that the data being extracted from the GP systems could identify a cohort of patients who had been seen recently by their GP. This

¹ Consolidated under the NHS Act 2006 Section 251

would reduce the sample size considerably and consequently the cost of undertaking the survey.

Members of the Advisory Group thanked him for his apology and agreed that the survey was an important activity, in providing both public accountability for the services provided with public funding and in giving patients a means to comment on access issues.

Members had a number of concerns, which were brought to the attention of Mr Armstrong. Members indicated that they shared the view of the BMA Ethics Committee that the fact of an appointment or referral is confidential information and therefore that extraction of data using this parameter constitutes a breach of confidence. Hence, Section 60 approval was required. There was acknowledgement that this was not in keeping with legal advice received by the Department. However, there are many areas where professional standards provide protection that exceed that afforded by law and this was one such case.

Members did not feel that the survey was described accurately by using the term patient experience, as the focus of the survey would be very narrowly on access. Members felt it would be more appropriate therefore to call it the GP access survey. Moreover, the Group felt it was important to be transparent that the survey is about payment for GPs. It was acknowledged that this might well polarise views but that this would be unlikely to result in a distortion and may, in fact, lead to a more accurate reflection of patient views. It was noted that there had already been media coverage of this survey that makes it clear that the purpose relates to GP payments. The Advisory Group believed it advisable to be honest with patients about this intention.

Serious concern was expressed about paragraph 16.4 in the guidance document recently issued by the Department which implies that, through discussion with the Secretariat, the activity has PIAG approval, when, in fact, the Group had not been formally consulted. Similarly, members were concerned about paragraph 16.5, which claims there is no breach of confidence. As indicated above, the Group disputed this.

Mr Armstrong listened to the Group's concerns and agreed to have early discussions with the Advisory Group and to submit an application for approval under Section 60¹ for data collection for the 2007/8 survey.

Following further discussion the Advisory Group agreed to ask that the Exeter system be used for this year's survey as this would provide the Advisory Group with assurance that no duty of confidence would be breached. In addition, that an addendum page be issued with respect to 16.4 and 16.5 of the guidance with future communications to GP practices to clarify that this has not been approved by PIAG and that the fact of an appointment is regarded as confidential.

[**Note from the Secretariat:** An issue that was not discussed at the meeting but has since been brought to the attention of Mr Armstrong was that of Stop-noted patients. Stop Notes are where demographic information such as name and address is withheld from systems outside the GP practice. With respect to Apollo, there was the issue of ensuring that stop-noted patients were not contacted about the survey without prior explicit consent. Allowing Apollo to extract their details without GPs having the opportunity to remove stop-noted patients prior to disclosure to Apollo and Mori is of serious concern. The particular sensitivities in relation to address details are such that this is a major factor in considering how to handle this in future. The Exeter system would not have such details and so stop-noted patients would be omitted via this route.]

4.4 NHS Information Centre National Infarction Angioplasty Project

The Secretariat reported that a letter had been received from the NHS Information Centre with respect to a new project being undertaken to analyse angioplasty data. This would require adding new clinical data items to the dataset already collected for the Healthcare Commission's Cardiac Care Audit. This would not include any additional identifiers. The Information Centre was seeking advice about whether or not this required 60¹ approval. As the Information Centre has no secure basis in law for its data collection currently, this would require an application. It was agreed, however, that as this was an uncontentious application it could be considered under the fast track application process, which would provide the Advisory Group with assurance about the security and confidentiality arrangements in place.

Action – Secretariat to inform the Information Centre of the Group's decision

4.5 Sapior Ltd

The Advisory Group had received a partial and draft application seeking approval in principle for an independent sector provider to establish a linkage and pseudonymisation service and obtain trusted third party status. The initial issue to consider was whether this fell within the scope of 'medical purposes' as defined by the Act. Legal advice proposed that this was for the Advisory Group to determine.

The Advisory Group's view was that whilst this may be regarded as within the scope of a medical purpose, as the proposed service was the purpose of the Secondary Uses Service and this would be a duplication. Moreover, the Advisory Group felt that what was being sought here was preferred provider status and members were clear that it was not the role of the Advisory Group to confer such status. Rather that it was the role of the Department of Health's procurement team, to identify appropriate providers, with guidance on

confidentiality and security arrangements from the Advisory Group and expertise within the Department.

Whilst recognising that there were benefits from good quality processing of data to verify data quality, undertake linkage and pseudonymise data effectively, members felt that an application such as this, would be unsupportable as it was seeking generic approval to process identifiable patient data, rather than the use of specified data for a particular project.

The Secretariat reported that this was in keeping with the previous discussions with the Department of Health's procurement team in establishing a framework of preferred providers undertaking Health Intelligence work on behalf of the Department and NHS bodies. In developing this framework, the Secretariat had advised on the confidentiality and security requirements to obtain preferred provider status. This would not obviate, however, the need to seek approval from either the Security and Confidentiality Advisory Group for access to Hospital Episode Statistics data and/or approval by the Advisory Group for access to identifiable data for specific projects.

Action – the Secretariat to advise Sapior Ltd of the Advisory Group's view.

4.6 MHRA, GP Research Database – record linkage of GPRD data with ONS death data and Small area level Townsend scores [3-04(i)/2006]

This application from the Medicines and Healthcare Products Regulatory Authority was to link the anonymised GP Research Database (GPRD) with ONS mortality data and allocation of deprivation scores based on postcode. The applicant had proposed that a trusted third party perform the linkage on their behalf so that the GPRD database would remain anonymised. When considered at the last meeting the third party had not yet been identified and therefore the Advisory Group were unable to make a judgement about whether the security and confidentiality arrangements of the proposed third party were appropriate and could be trusted. Following negotiations, the applicant had responded to propose that the Information Centre become the trusted third party. This was regarded as an acceptable approach by the Advisory Group; however, members wanted to see a revised application including details of the security and confidentiality arrangements as it was reported that the policies for the Information Centre were not confirmed as having been formally adopted by the Information Centre and this would be a pre-requisite for approval. Stronger user involvement arrangements were again highlighted as an essential component.

Action – Secretariat to inform the applicant of the Group's decision

4.7 NHS Information Centre

The Secretariat reported that there had been a meeting with staff at the NHS Information Centre (IC) with respect to their use of confidential patient data for secondary uses. It was noted that the Information Centre was in the process of merging with NHS CfH's Secondary Uses Service and that most of the staff were being re-located to Leeds. The functionality of HES would continue however, under the new arrangements. A number of issues had been discussed including the problems associated with sub-contracting arrangements. It was noted that for project-based activities S60 applications would be submitted for both commissioned bodies and internal IC activities under the class regulations where they were applicable. It was noted that this would be likely to generate a substantial number of applications.

In particular, it had been suggested that as the Information Centre already had access to the data a generic application should be submitted to cover the HES data cleansing and pseudonymisation service for medical researchers etc. This would provide a secure lawful basis for staff access to data for the purposes of de-duplicating, validating and linking data so that what was disclosed was effectively pseudonymised data.

4.8 Social Care Update

The Advisory Group considered an update providing an overview of social care and the points of intersection with health in relation to the use of patient data. Members were concerned that consent seemed to have been omitted and that the issues in relation to interface with the independent sector needed more attention. This raised significant and fundamental questions such as 'What is a health record?' This had been considered by the Care Record Development Board in July, where the view taken was that the definition included in the Data Protection Act (DPA) below was likely to take precedence over others:

"Health record" means any record which-

- (a) consists of information relating to the physical or mental health or condition of an individual, and
- (b) has been made by or on behalf of a health professional in connection with the care of that individual.

It was agreed that consideration should be given to the issue of confidential patient information initially recorded by a clinician in a healthcare setting but which may subsequently be disclosed to and recorded within a social care setting. Where confidential health information has been disclosed to others, this would appear to remove its status as confidential health information by virtue of it being recorded elsewhere, which would not be keeping with the intention of legislation.

It was agreed to consider this question further at the March meeting and to invite Mr Tooher from the Department of Health to attend the meeting.

Action – Secretariat to invite Mr Tooher to the next meeting

4.9 Membership

In light of the fact that the legislative changes to the National Information Governance Board had been put on hold for at least twelve months, it was agreed that the Advisory Group should issue directions for the appointment of three new members. The Advisory Group had previously lost two members, which had not been replaced pending the outcome of the Information Governance Review and its consequent changes. It was noted that the original members were also due to step down before December 2007 and therefore that there was value in undertaking a recruitment process as soon as possible to ensure continuity and to phase the appointment of new members.

Action – Secretariat to issue directions to the Appointments Commission

4.10 Secondary Uses Service revised Regulations

Following discussion of the Secondary Uses Service application for S60¹ support, the Advisory Group proposed that consideration should be given either to the Secondary Uses Service seeking a lawful basis for its activities through primary legislation or through specific regulations under S60¹. Subsequent to this, it has been agreed that it is unlikely the Secondary Uses Service will need a permanent basis in law for access to identifiable data as, in time, access will only be permitted where there is a secure basis in law.

Further to this, a number of other uses of data not covered, either by the class regulations or by way S60¹ has been framed, have been identified. It has been mooted therefore that consideration should be given to how, either the class regulations or primary legislation might be re-framed to encompass such uses.

Action – Secretariat to discuss this further with the Secondary Uses Service

5. Chair's Report

The Chair reported that the MRC commissioned research undertaken by MORI on the use of patient information for research had been completed and the report presented to the MRC Steering Group. The Chair reported that the steering group was currently considering how to disseminate the results and that it was hoped this would be published in January / February 2007.

6. Information Governance Review Update

The Chair welcomed Mr Philip Brown who had attended to update the Advisory Group on progress in relation to the implementation of the Information Governance Review. Mr Brown reported that the proposed Autumn Health Bill had been deferred and consequently the legislative changes necessary to create the National Information Governance Board postponed. It was likely that the Board would be developed as an advisory body in the meantime but without a statutory basis, with a view that legislation could be brought before Parliament in autumn 2007. A paper outlining options had been presented to the Minister for consideration but that no decision had been reached yet.

The Advisory Group would therefore continue unchanged for the time being but that once an option had been agreed, there would need to be discussions with how the new body would work in conjunction with the Advisory Group. Mr Brown undertook to inform the Group once a decision had been reached.

It was noted that in relation to the development of the Caldicott Guardian's role that proposals had been put together for consideration by Professor Martin Marshall, the Deputy Chief Medical Officer (DCMO) and Department of Health Caldicott Guardian.

7. Applications previously considered

7.1 Cancer Research UK (Leeds Teaching Hospital Trust) – A retrospective case-control study of melanoma patients who have undergone sentinel lymph node biopsy [3-4(b)/2006]

This study, to increase understanding of Sentinel lymph node biopsy (SNB) in providing prognostic information for patients and their carers was considered at the September meeting and given partial approval. The Advisory Group considered a letter from the applicant providing further information. Members discussed the issue of what role costs should play in the decision-making of the Advisory Group and whether or not there might be another alternative to the two proposed approaches. It was agreed that the Secretariat in consultation with Professor Catchpole should have further discussions with the applicant to see if another approach was practicable. It was noted that another study had recently been published demonstrating the appropriateness of SNB and therefore it was proposed to seek clarification from the applicant whether there was still benefit to pursuing the study as currently framed. It was agreed that, provided the study was still of benefit and an acceptable solution could be found in consultation with Professor Catchpole, this application could be approved by Chair's action, subject to appropriate security arrangements and agreement to undertake user involvement.

Action: Secretariat to have further discussion with the applicant in consultation with Professor Catchpole

[**Note from the Secretariat:** This application has subsequently been approved by Chair's action to facilitate one data extraction process but with consent being sought from those still under care or recently discharged prior to analysis being undertaken.]

7.2 Clinical Trials Support Unit, University of Oxford – HPS2 – THRIVE: Treatment of HDL to Reduce the Incidence of Vascular Events [3-04(f)/2006]

This application was for a study to assess the effects of raising HDL cholesterol with niacin plus MK0524 to offset the side effects of niacin, in order to reduce the risk of cardiovascular events, in people who already have a history of such events or risk factors. The application was to identify the relevant cohort in order to seek their consent to participate.

Following the provision of further information from the applicant as to why consent was not practicable, the Advisory Group agreed to support the application on this occasion. Concern was expressed however, that this should not be taken as establishing a precedent. Members felt that it was important to be clear that there is a requirement on the NHS to move towards establishing mechanisms for seeking consent, in particular where there are collaborating centres and clinician involvement. It was agreed in light of this to seek a meeting with the applicant to discuss these issues further.

The approval would be subject to the following conditions:

- More is done with respect to user involvement
- The removal of data about dissenters and unsuitable candidates immediately, and non-responders at the end of the recruitment period.
- Satisfactory security arrangements.

Action – Secretariat to inform the applicant of the Group's decision

7.3 Queen Mary, University of London – A case control audit to evaluate the impact of the NHS Breast screening programme in the W Midlands on women's risk of dying of breast cancer [3-04(g)/2006]

This application involved a comparison of screening histories of cases and controls through linkage of data held by the West Midlands Cancer Intelligence Unit, NHAIS (Exeter) and the National Breast Screening Service. Identifiers were only required for a short period to undertake linkage, establish vital status, whether they were still living in the region and to undertake some preliminary analysis such as deriving deprivation scores from postcode. The applicant had provided further information and clarification that this was part of the national programme and integral to its quality assurance, and had been reviewed by a research panel.

The Advisory Group agreed to approve the application subject to ongoing user involvement and evidence of the nature of the review undertaken.

Action – Secretariat to inform the applicant of the Group's decision

8. Fast track applications

8.1 BPSU: Vitamin K deficiency bleeding - Child Health, Royal Devon & Exeter NHS Foundation Trust [BPSU PIAG 4-06(FT1)/2006]

This application from Dr J Tripp at the Child Health Department of the Royal Devon & Exeter Hospital was for a study using the BPSU methodology. The identifiers required were Hospital of birth, Hospital number, date of birth and gender. It was approved under the fast track application process by Chair's action subject to the following conditions:

- Confirmation of secure transfer of data to the research team
- Clarification of which identifiers will be removed.

8.2 Self-harm monitoring project - Derbyshire Mental Health Trust [PIAG 4-06(FT2)/2006]

This application was an extension of the Oxford Self-harm monitoring project to a new site at Derbyshire Mental Health Trust. This multi-centre study also includes Manchester and Leeds. This application required access to health records within A & E settings to identify patients who had self-harmed and to extract a pseudonymised dataset, including age, gender, a broad categorisation of ethnicity and occupation and local authority of residence only. A new aspect of the study was flagging on the NHS Central Register. Identifiers would be sent to the ONS for flagging but data would be returned to Derbyshire Mental Health Trust. The Trust would hold the key to identifiers, thus enabling ongoing linkage. This aspect would be the subject of an application to the ONS Advisory Group for all the centres. Patient Information Leaflets would be made available in A & E and Mental Health Service clinics. It was approved under the fast track application process by Chair's action subject to the following conditions:

- Satisfactory security arrangements with regard to encryption.
- Ongoing access for longitudinal linkage needs to be considered to obviate the need for ongoing access by a researcher.

8.3 Mental Health Act Commission Census [PIAG 4-06(FT3)/2006]

This fast track application was to repeat the Census undertaken for the last two years. It was noted that there were no substantive changes proposed from last year's data collection. However, although approved last year, concern had been expressed about the appropriateness of asking patients and collecting data about their sexual orientation because of the sensitivity of this data. It was recognised that this can be clinically significant and so permission had been given. The Advisory Group asked to revisit this aspect this year in light of what had been learnt from the previous census, to consider whether it was still appropriate that this be collected as part of the census. Following discussion of the issues and safeguards in place, the Advisory Group agreed to approve the application.

Action – Secretariat to inform the applicant of the Group’s decision

9. New applications

9.1 UK Biobank [PIAG 4-06(b)/2006]

The Group welcomed Professor Rory Collins from UK Biobank who attended the meeting to answer queries regarding the application. He updated the Advisory Group on the recently completed pilot, which covered:

- The difficulty of getting the data locally from PCTs. Professor Collins explained that they had only received data from two out of the four PCTs, one quickly and one after a couple of months.
- The need to develop a mailing system that would avoid sending duplicate mailings; reduce the likelihood of inviting deceased patients and improve socio-economic sampling facilitated through the use of the NHS number and postcode.
- The process for dealing with complaints/queries and what had been learned from correspondence received so far.

Members asked a range of questions including whether it was necessary to obtain the NHS number and the name and address of a patient’s GP? Professor Collins explained that whilst these were not essential pieces of information, having GP contact details reduced the mailing costs of informing GPs in the area by 30%. He indicated that GP details did not need to be linked back to individuals but only at a collective level of those included on an invitation database. The NHS number was requested, to de-duplicate records and to facilitate checking potential invitees’ vital status shortly before the invitations went out in order to remove those who had died and reduce the likelihood of distress to recently bereaved families.

The Advisory Group, whilst acknowledging that there was lay and patient input via the Ethics and Governance Committee, felt that there would be benefit in the International Scientific Advisory Committee having patient and lay involvement. Professor Collins agreed to consider how user involvement might be further strengthened.

It was noted that, in giving consent, people would be giving up all Intellectual Property rights in relation to their data. Members asked what rights and recourse participants would have if the terms of what was being undertaken changed. In particular, who would own the Intellectual Property (IP) if in the long term UK Biobank came to an end. Professor Collins responded that any major changes would need to be approved by the independent Ethics and Governance Committee, including determining what would happen to the IP rights. Additionally, there would be communication with participants on an ad hoc basis about significant changes and participants had a number of options to withdraw their participation if they became unhappy about a decision reached on a particular issue.

It was acknowledged that it was debateable whether S60 was required legally, the Advisory Group felt however, it was appropriate given the proposal to use the NHS

number and GP details and to minimise any uncertainty about the lawfulness of disclosure.

The Advisory Group welcomed the lessons that had been learned through undertaking the pilot and testing the feasibility of working with PCTs to facilitate recruitment. The work that had been undertaken in ascertaining the reasons for declining participation and testing people's understanding of to what they were giving consent, was particularly well received. Members were reassured by the fact that UK Biobank had adopted an iterative process and would continue to learn from experience as the project developed. The Advisory Group accepted the argument that the NHS number was important, both because of the scale of numbers involved in the project and to clarify vital status so that distress to recently bereaved relatives would be minimised (c.150 families instead of c.1000). Members remained concerned that significant abnormal results of blood and urine test would not be reported to the participant's GP but were aware that this was outwith the Advisory Group's remit. Similarly, members were concerned about the representativeness of participants and suggested that further consideration be given to addressing health inequalities, in particular in relation to rural deprivation.

In the light of these considerations, the Advisory Group agreed to approve the application subject to the following conditions and on the clear understanding that this was an exceptional case and therefore that it should not be taken as setting a precedent for other studies:

- That the letter to invitees was amended to make it explicit that it is highly unlikely that the individual will benefit from this research. Members felt that the phrasing implied that the study might help individuals and that the wording could be more direct.
- That the letter to GPs would make it clear that, the NHS number would be disclosed as well as contact details.
- Members felt that it would be preferable to obtain GP details relating to a local cohort of patients rather than to individuals' details prior to consent, if feasible this approach should be adopted.
- That decliners are differentiated from non-responders both in how their data is handled but also in terms of future reporting.
- That those declining to participate must be informed that their details will be retained during the recruitment phase so that Biobank know not to re-invite them or if they decline this to understand that they may be re-invited. Consideration should be given to retaining only the NHS number as a compromise. We would advise that a note to this effect is included on the reply form.
- That consideration is given to further improvements in lay involvement in particular in relation to the International Scientific Advisory Committee.
- Satisfactory security arrangements.

Action – Secretariat to inform the applicant of the Group's decision

9.2 University of Newcastle - Long term sequelae of radiation exposure from Computed Tomography in children and adolescents [PIAG 4-06(c)/2006]

The Advisory Group considered this application from the University of Newcastle to extract data from medical records and link with data held by cancer registries and NHS Central Registry data. This was the national roll out of a previously approved pilot study, to determine whether there was an increased risk of developing cancer following radiation exposure from CT scans.

The Group noted that a large volume of clinical data was being collected, and questioned a) whether this was necessary and b) whether this information could be coded. It also noted that data was intended to be held for 15 years, and queried whether this information could be pseudonymised and flagged on NHSCR – therefore reducing the identifiability of data much more quickly than the proposed 15 years. No confirmation of ethical approval was provided with the application. However, the Advisory Group agreed that this was a valuable study and that attempting to obtain consent could raise undue concern amongst patients. The Advisory Group therefore agreed to approve the application subject to the following conditions:

- Confirmation that the study has research ethical approval
- User involvement with a relevant patient group
- To develop an exit strategy in the first year to obviate the need for long-term retention of identifiers such as via the NHSCR. This will need to be addressed satisfactorily at the first annual review for S60¹ approval to continue.

Action – Secretariat to inform the applicant of the Group’s decision

9.3 University of Salford - Experiences of changed medication appearance amongst older people [PIAG 4-06(d)/2006]

The Advisory Group considered this application to undertake a survey of patient experience of the changed appearance of medicines. The applicant required support to obtain an extraction from GP systems of name and address of patients taking three or more types of tablet medication in order to send out questionnaires to them.

The Group was concerned about the design of the study and asked for confirmation that the research has been reviewed by an Internal Review Panel and for the outcome of this review to be submitted.

The applicant also wished for the letter accompanying the questionnaires to come from Age Concern rather than the GP. This would be contrary to one of the Advisory Group’s key principles that the first point of contact should come from an organisation with which the patient had a relationship. Members were not persuaded to override this principle based on the arguments presented.

Given the relatively small scale of this study, the Advisory Group therefore rejected this application and proposed that following appropriate consideration by an Internal

Review Panel, the applicant should arrange with the GP practices for them to send out the questionnaires with a covering letter from the practice.

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

9.4 Velindre Trust, Wales - New Born Hearing Screening Wales Evaluation [PIAG 4-06(e)/2006]

The Advisory Group considered this application for Section 60 support from the Velindre Trust, Wales for a national screening programme to test for significant hearing impairment in newborns and symptomatic significant hearing impairment in children up to 5 years.

There was concern that the researchers intended to share the data collected with other researchers and the Group wanted to make clear that applications for Section 60¹ approval did not permit subsequent disclosure of identifiable data to others.

The Advisory Group agreed to approve the application subject to confirmation of the above and the following conditions:

- Confirmation of appropriate security arrangements including data destruction
- Clarification of how soon the data would be anonymised
- Moving towards using the NHS number for subsequent matching

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

9.5 Dept of History & Philosophy, University of Cambridge - A history of psychiatric and psychotherapeutic practice in London from 1945-2006 with particular reference to the treatment of children and adolescents [PIAG 4-06(f)/2006]

This application was for a historical review to identify trends and changes in practice over time and the reasons for them, identify areas of weakness and strength in service provision and aid the management of health and social services.

The Advisory Group had a number of concerns that this study was rather ambitious in its aims. It was noted that the user involvement was poor. The Advisory Group agreed that although borderline, to accept on this occasion that this could be encompassed within the scope of 'medical purposes'. The study was approved subject to the following conditions:

- Confirmation of appropriate review by an Internal Review Panel
- Confirmation of Research Ethics Committee approval
- To undertake user involvement with a relevant patient body e.g. Young Minds

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

9.6 Southwark PCT - Development of geodemographic health management of chronic diseases [PIAG 4-06(h)/2006]

This application was to apply innovative technology to geography in order to identify patients at risk of hospitalisation.

The application was requesting full postcode, however the Group questioned whether census output and super output would be suitable instead. It was also noted that user involvement was poor for this project.

The Advisory Group agreed to approve the study subject to confirmation that full postcode is necessary.

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

9.7 Lancs. & South Cumbria Cancer Network - PCT CDS Extract Request [PIAG 4-06(i)/2006]

This application was to facilitate baseline assessments over 12 months allowing the cancer network to map patient pathways between Trusts, and the flow of the responsible population to other Networks.

A draft application was submitted to the Advisory Group. The Secretariat reported that a revised version had subsequently been received. The Advisory Group agreed to consider the revised application after the meeting, as it seemed straightforward and to resolve by Chair's action if this was appropriate.

Action: Secretariat to circulate revised application following the meeting for consideration

[Note from the Secretariat: This application was considered by members and subsequently approved by Chair's action subject to the following conditions:

- Unless the data is anonymised, consideration of how to handle where issues arose from the case note review that were of significance to how patients were being treated and remedial action was possible. Mechanisms to address these issues in conjunction with treating clinicians should be put in place where this is the case.
- Clarification of what user involvement is in place
- The development of a patient information leaflet to be placed in paediatric / oncology clinics aimed at the subset of patients in which they are interested.
- Satisfactory security arrangements being in place including the secure transfer of data.
- Non-disclosure of identifiable data to the Department of Health.]

9.8 London School of Hygiene & Tropical Medicine – Does the implementation of treatment guidelines affect cancer survival? [PIAG 4-06(j)/2006]

This study was to compare data on cancer standards and patient survival from Trusts in three regions of the UK in order to assess explanatory relationships with adjusted relative survival for four common cancers (breast, bowel, lung, prostate) using multi-variable regression models.

The Advisory Group agreed this was an important question but were concerned that this study may have difficulty in establishing causality, as there were no control groups. As the study had been through appropriate scientific review, however, the Advisory Group agreed to approve the study subject to appropriate security arrangements including the use of encryption for secure transfer.

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

9.9 LSHTM – Air pollution-related health effects of the London Congestion Charging Scheme [PIAG 4-06(k)/2006]

This study was to undertake small area geographic analysis of emergency admissions and deaths data from HES and ONS with air pollution data in London before and after the introduction of the congestion charging zone (CCZ). This required access to postcode and clinical data related to emergency hospital admissions and cause of death, in particular for cardio-respiratory symptoms.

There were concerns from the Group regarding scientific and statistical validity of this study and again felt there would again be difficulties with establishing causality, given that thresholds for admissions had changed. However, as the study had been reviewed scientifically, the Advisory Group agreed to approve the study subject to the following conditions:

- Clarification as to whether full postcode was indeed necessary.
- Appropriate security measures in place.

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

9.10 University of East Anglia - Deprivation and exception reporting in 2003 GMS contract [PIAG 4-06(g)/2006]

This study was to identify if there is a link between deprivation and exception reporting which would indicate whether the GMS contract has exacerbated health inequalities. This required access to GP disease registers and postcode / address information to examine whether in a particular disease register patients who are more deprived (and thus have a greater health need) are more likely to be exception reported from receiving beneficial interventions covered by the new GP contract clinical indicators. The Advisory Group welcomed how the applicant had engaged with patients in relation to this study. Following consideration, the Advisory Group agreed, as there was no other way to undertake this study and access was time-limited, to approve the application.

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

10. Complaints and appeals

10.1 The Advisory Group considered correspondence complaining about the decision-making of the Advisory Group although not in relation to any particular application. It was agreed, the Chair would respond on behalf of the Advisory Group. It was further agreed that in relation to how complaints should be handled, that they should be sent to the Chair for response, as had been the case in this instance.

Action – Chair to respond to complainant

The Advisory Group considered whether an appeals process or internal review process was the most appropriate way to proceed. It was noted that the impetus for an appeals process had come from the Parliamentary Ombudsman as a requirement for all Arms Length Bodies. Members felt, however, that this was impracticable as all members of the Advisory Group were involved in deciding almost all the applications. It was also felt that the informal approach of working with applicants to find a solution had in general worked effectively. It was noted that applicants still had a means of recourse if they continued to be dissatisfied through the Parliamentary Ombudsman. The Advisory Group could also refer intractable issues to the Secretary of State for Health. It was agreed therefore to adopt an internal review process in order to go some way to meeting the requirement for an appeals process.

Action – Secretariat to finalise the Internal Review Process document

11. Fast track application process

A revised Fast track application process document was considered and approved.

12. Future meetings for 2007

Awayday Monday 5th March 2007

Tuesday 6th March 2007

Monday 11th June 2007

Wednesday 12th September 2007

Tuesday 4th December 2007