Minutes

PIAG
Patient Information Advisory Group

Meeting held on Tuesday 5th February 2008

Present:

Members: Professor Dame Joan Higgins (Chair), Dr Tricia Cresswell, Ms Stephanie Ellis, Mr Michael Hake, Ms Ros Levenson, Ms Barbara Meredith, Professor Sir Denis Pereira-Gray, Dr Peter Rutherford, Dr Patrick Coyle, Dr Mark Taylor, Mrs Pauline Brown, Mr Terence Wiseman, Dr Fiona Douglas, Ms Susan Parroy.

In attendance: Miss Anoopa Bharath (Secretariat), Ms Melanie Kingston (Secretariat), Mr Sean Kirwan (DHIPU), Mr John Sheehan (Secretariat) and Ms Karen Thomson (Secretariat).

1. Welcome and Apologies for absence

1.1 Apologies for absence were received from Professor Roy McClelland **&** Professor Mike Catchpole.

2. Minutes of last meeting

2.1 Minutes of the previous meeting held on 4 December 2007 [PIAG 4-02/2007] were agreed to be an accurate record, subject to minor amendments.

3. Secretariat report

The Secretariat report was received and its contents noted.

3.1 <u>ONS Advisory Group for Medical Research (AGMR) – transfer of responsibilities back to PIAG</u>

With the transfer of the NHS Central Register from the Office for National Statistics (ONS) to the Information Centre for Health and Social Care, the Advisory Group considered the options presented by the Secretariat with respect to future approvals for flagging and tracing on the NHS Central Register (NHSCR). Under the previous arrangements, the ONS Advisory Group for Medical Research was given delegated authority under their 2002 class support [PIAG 4-07(h)/2002] to cover historical studies flagged on NHSCR and asked to establish an advisory group to review the continued need for these flags. PIAG had asked that the ONS Advisory Group to establish whether or not valid consent was in place or could be obtained for these studies and to consider applications for new studies requiring support under Section 60 for the limited purpose of flagging and tracing. It had been agreed that this delegated authority should not transfer to the Information Centre for Health and Social Care but revert to PIAG. A number of options for how the Advisory Group could manage these applications were considered.

Members agreed that where valid consent was in place and there were no issues relating to the application, these would be checked by the Secretariat and would then be implemented by the Information Centre. Where there was a question, regarding the validity of the consent obtained or where there were other information governance concerns, these would be considered by the Database Monitoring sub-Group (DMsG)[1] on behalf of PIAG and in line with the sub-Group's oversight function for the national databases. Applications without valid consent, or where there were issues that could not be resolved by the Database Monitoring sub-Group, would be considered by PIAG, although straightforward S251 applications would be routed through the fast track route. This process would be kept under review and altered once the Advisory Group and DMsG had had a chance to familiarise themselves with the application process and the particular nature of these applications.

Action: Secretariat to draft guidelines and processes for ONS applications.

3.2 Database Monitoring sub-Group

Terry Wiseman and Ros Levenson agreed to become members of the DMsG.

The Advisory Group requested that the DMsG review the current list of identifiable and sensitive HES data items to see if any changes should be made to this list e.g. date of death might be regarded as an identifier. The Advisory Group also requested that the DMsG review the current list of precedents set by the ONS.

ACTION: Review of sensitive HES data items and precedents set from ONS to be put on agenda for next DMsG meeting.

3.3 Sexual Health PbR/commissioning advice

Following discussions between the Secretariat and the Sexual Health and Payment by Results teams in the Department, draft advice about the use of identifiers for Payment by Results (PbR) in relation to Sexual Health clinics was presented to the Advisory Group for consideration. Members did not agree with the proposed advice indicating that the use of any identifiers in relation to sexual health data for PbR or Commissioning purposes was not acceptable and provided comments on how the advice might be re-drafted to reflect this. It was agreed the revised advice could be approved by Chair's action.

ACTION: Secretariat to revise guidance and obtain approval by Chair's action prior to dissemination

3.4 Health Protection Agency – Audit of Malaria mortality

The Secretariat had received a query from the HPA regarding this audit. This is a new audit and the HPA requested confirmation that this work was covered under their existing approval. Members agreed that this work could be undertaken under the HPA's existing approvals.

ACTION: Secretariat to write to HPA to confirm the above.

3.5 Approval Extensions

No extensions had been granted to existing applications since the last meeting.

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[1] Group formerly known as the Security and Confidentiality Advisory Group

3.6 Identifying research participants

Members discussed the responses to the Advisory Group's consultation on identifying relevant patients for medical research. A key area of contention identified is the Advisory Group's position that as researchers and research support staff are not involved in the direct routine care of patients, they are not part of the clinical care team. They therefore have no legitimate basis for accessing identifiable patient information without the explicit consent of the patient. Members reaffirmed that issuing an honorary contract to researches does not automatically make them part of the clinical care team. Only staff employed on substantive contracts and involved in the direct routine care of a patient can be considered part of the clinical care team.

Members recognised that utilising clinicians to identify cohorts for research could be difficult as many clinicians do not have the time or are unwilling to do this. It was noted that there was strong disagreement from the research community and the Department's Research and Development team to this. Members considered how this might be addressed and following discussion agreed that a meeting should be set up to discuss this particular issue with a view to finding a way forward that was acceptable both to the research community, to the Advisory Group and to the public.

ACTION: Secretariat to arrange a small meeting to discuss this issue with DH RDD, UKCRN and a few other key stakeholders.

3.7 Consultations

Data Sharing Review Consultation

It was noted that Mr Richard Thomas and Dr Mark Walport were conducting a consultation on the use and sharing of personal information in the public and private sectors as part of their independent Data Sharing Review. It was agreed in light of deadline that the response would be approved by Chair's action.

GMC Confidentiality Consultation

The GMC have begun a consultation on their guidance "Confidentiality: Protecting and Providing Information". Members have been asked to comment on this consultation. It was agreed in light of the deadline that the response would be approved by Chair's action.

ACTION: Secretariat to revise / draft responses for circulation and approval by Chair's action.

4. Chair's Report

4.1 GP Patient Experience Survey

The Chair reported on the response from the minister with respect to the Advisory Group's decision regarding the GP Patient Experience Survey. It was agreed that the Chair should write to the minister to clarify what methodology had been used.

ACTION: Chair to write to the minister.

4.2 National Child Measuring Project (NCMP)

It was noted that this project had now been included within the Health and Social Care Bill and that the advice given both by the Advisory Group and by the National Screening Committee had not been accepted by ministers.

ACTION: Chair to write to the minister to express the concerns of the Group.

5 Applications previously considered

5.1 Iron deficiency anaemia and delayed diagnosis of colorectal cancer [PIAG 4-05(k)/2007]

This application was considered by the Group at the last meeting. The application was presented in two parts, a feasibility study and a definitive study. The Group gave partial support for the feasibility study for those who were no longer registered and requested that a separate application be submitted for the definitive study. The applicant had submitted further information and asked the Advisory Group to re-consider this application.

Members discussed this application paying particular attention to the suggestion that seeking consent may introduce study bias. Members were not convinced by the arguments regarding data bias. Members noted that only between 5% and 14% of the notes to be accessed would relate to patients who have cancer; this would result in the applicant viewing a large number of irrelevant case notes. This group felt this was unnecessary and that a different approach that was more targeted at only reviewing notes of patients with colorectal cancer was preferable and should be considered.

The Advisory Group agreed exceptionally to approve the application for the feasibility study, provided that the study looks properly at biases and have requested that a meeting be arranged to discuss the results of the feasibility study once completed and to consider the best approach for the full study.

ACTION: The Secretariat to advise the applicant of the Group’s decision.

5.2 An evaluation of the effectiveness of different treatment pathways and service provisions for adolescents with eating disorders [PIAG 4-05(m)/2007]

This application was first considered by the Group at the meeting in December. The application was presented in two parts, 1) to access retrospective data and 2) to access prospective data. The Group did not approve the application for prospective data and requested clarification of why retrospective data was necessary for this study.

The Advisory Group considered this revised application and rejected the application as they felt that reasonable alternatives to Section 60 support existed.

Members felt that the main purposes of this research study were to assess and/or evaluate services for adolescents with eating disorders, and they believe that evaluation of any services requires input from patients. As service evaluation requires patient involvement and that this cohort are in contact with health care workers, obtaining consent appeared to be a reasonable alternative.

Members were further concerned that if Section 60 approval were given that it may, in fact be overriding dissent. As there is direct link between this cohort and health care workers, there are opportunities to obtain consent.

Furthermore, Members questioned why this study could not be undertaken with retrospective data, which could be fully anonymised thus negating the need for Section 60 approval and the need to seek consent from patients.

ACTION: The Secretariat to advise the applicant of the Group's decision.

5.3 IMS Health and HES data linkage [PIAG 4-05(e)/2007]

The Chair declared an interest in IMS Health and asked Professor Sir Denis Pereira-Gray to chair the discussion for this application. The Advisory Group considered this revised application and approved it subject to the following clarifications and conditions.

- The applicant to provide clarification as to what is meant by the patient ID that is referred to in Extraction 1 of the supporting information, figure 2 specifically how is this created and how this is pseudonymised.
- The applicant is to clarify whether full or partial postcode is to be received by the IC, and whether full or partial postcode is to be retained by Northgate in relation to this linkage work.
- The applicant needs to complete sections (r) and (s) of the application form adequately.

It was agreed that formal approval of the application, following the above conditions being met satisfactorily, would be provided by Professor Sir Denis Pereira-Gray taking deputised Chair's action in this instance.

ACTION: The Secretariat to advise the applicant of the Group's decision.

6. Summary of fast track applications

It was noted that no fast track applications had been received since the last meeting.

7. New applications for Section 60 support.

7.1 HES Application [PIAG 1-05(b)/2008]

The Advisory Group considered this application and agreed to provide approval on a temporary basis, subject to conditions, whilst a more permanent basis in law was established. Members felt that as there would be an ongoing need for a small central team to have access to the data for data cleansing and quality assurance purposes and given the breadth of uses for HES, there was a need for a more permanent and robust legal basis than under the class support regulations. This could be obtained either through primary legislation or through specific regulations under Section 251 laid before Parliament. Either of these routes would engage the democratic process and provide opportunities for public scrutiny and hence would provide a more secure legal basis.

Members agreed to approve the application subject to the following conditions:

- Dr Patrick Coyle, as Chair of the Database Monitoring sub-Group (DMsG), was not an appropriate sponsor as he is not responsible for the work undertaken by the Information Centre. A more appropriate sponsor would need to be identified. This should be the senior responsible officer within the Department for commissioning the work undertaken by the IC in relation to HES.
- That support under Section 251 would not permit onward disclosure of either sensitive or identifiable data to any third party without the approval of PIAG for identifiable data or DMsG for sensitive but non-identifiable data.
- That the Information Centre establish a patient group to discuss the potential issues relating to HES Data. This group must be fully established within the next twelve months.
- That this approval is only for established NHS and research purposes. New activities would need to be agreed separately by the Advisory Group[2].
- A more detailed response to question (r) addressing how the requirements of the DPA would be met.
- The Information Centre must promote public awareness of the aims and usage of HES Data. It was suggested that a presence on the Departmental, Directgov and other similar websites, even if only signposting people to the HES webpages would go some way to achieving this.

The Advisory Group emphasised that it is imperative that the Information Centre pursue a permanent basis in law for the HES database.

ACTION: The Secretariat to advise the applicant of the Group's decision.

7.2 National registry of babies born with a cleft lip and/or palate (part of the CRANE Database) [PIAG 1-05(c)/2008]

The Advisory Group considered this revised application but did not approve the application, as the previous comments raised during discussion with the applicant did not appear to have been taken into consideration in presenting a revised application.

Members acknowledged their support for this work and felt Section 251 support would be appropriate for the initial notification process that a baby had been born with a cleft lip and/or palate, for the purpose of surveillance (i.e. monitoring numbers). This was subject to the caveat that the information collected was kept to a minimum, both in terms of clinical details and identifiers. However, members felt that they could not approve the initial notification process based on the applications received to date.

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[2] If similar to previous activities, it might be possible for this to be considered on the basis of a protocol or similar document, provided sufficient detail is included relating to the aspects likely to be of concern to the Advisory Group. New activities however are likely to require a full application.

Members felt that as children with this condition would be in regular contact with a clinician, there would be multiple opportunities for clinicians to seek the consent of parents at an appropriate point in the care pathway. Where parents refuse to give consent then all identifiable information previously collected for the notification should be removed. Effectively anonymised information could be retained. Moreover, members felt that the Registry could use the notification collection process to remind clinicians that they need to obtain the consent of parents.

Members indicated that there are registers in existence e.g. for Cerebral Palsy, which are fully consented, thus demonstrating that consent is practicable and providing an example of good practice.

Members were also concerned about the need to obtain consent from children on the register as they attained competency. Members suggested that competency should be assessed from the age of 12 upwards and capacity assumed from the age of 16 as required by the Mental Capacity Act and therefore that consent should be sought from children no later than the age of 16 unless they are assessed as lacking capacity.

Members requested that the applicant submit a revised application to cover just the initial notification process, specifying the minimum clinical data needed and the minimum identifiers needed with justification.

ACTION: The Secretariat to advise the applicant of the Group's decision.

7.3 European Prospective Investigation into Cancer (EPIC – Oxford) [PIAG 1-05(d)/2008]

This study was original set up in 1993 and all participants consented to taking part in the study. The original consent forms included consent for the researchers to obtain the diagnosis of cancer but did not specify any further information, therefore, PIAG approval was granted in 2003 to obtain further information regarding cancer diagnosis [PIAG 3-09(e)/2003].

This application is to extend the information held. The applicant had requested permission to obtain HES records of all diagnoses made and procedures performed in hospital for the 60,000 participants in the original study.

Members were not confident that the original consent form signed would cover this new use of data. The main concern was that the original patient information leaflet given stated that data would be held for 10 years and this study would be significantly extending the period of data retention. However, members were also sympathetic that this was a large study population and attempting to regain consent of all participants would be impractical.

The Advisory Group agreed that EPIC should obtain a sample of approx 200 people from the original cohort to establish whether they would be wiling to provide their consent for the extended use of their information. This would enable EPIC to establish whether patients from the original cohort would be happy for their information to be used for this further study. The Advisory Group agreed that the applicant should be asked to indicate what criteria would be used to ensure that the sample group was representative of the whole cohort.

Whilst recognising that this is extending a historical study, members were also concerned that this study excluded people who do not speak English and therefore questioned whether this study would be compliant with the Race Relations Amendment Act and proposed that the applicant be asked to seek advice on this.

ACTION: The Secretariat to advise the applicant of the Group's decision.

7.4 Independent Sector Treatment Centre Audit [PIAG 1-05(e)/2008]

The Advisory Group considered this application and whilst the Advisory Group acknowledged the importance of this study, members did not feel they could approve it. Members were concerned that "consent unknown" would include patients who had withheld their consent and had previously indicated on numerous occasions that Section 251 support was not to be used to override patient dissent.

Members also discussed the issue of study bias and whilst they appreciated that sometimes bias may occur, Members were not convinced that bias would necessarily occur in this study and no evidence had been provided to support this assertion. Members felt that the concern that study bias is a possibility is not sufficient reason to set aside the common law duty of confidentiality. It was agreed therefore that this audit should be undertaken with consent and that if evidence of bias is identified during its course e.g. in a particular service or sector, then the Advisory Group would be willing to consider an application to address this. Any revised application should additionally address the issue of how to ensure that patient dissent is respected.

Additional comments from members were that this was an audit and therefore substantively different from the National Joint Registry (NJR), which had been referred to in the application. Additionally, the minutes pertaining to that application had made it very clear that the NJR approval was exceptional and only provided because of the efforts that had already been made and continued to be made with respect to obtaining and recording consent.

It should be noted that the Advisory Group makes decisions on a case-by-case basis and the balance of the different factors the Advisory Group considers can be subtly different and hence can lead to a different outcome in what superficially would appear to be similar uses.

ACTION: The Secretariat to advise the applicant of the Group's decision.

7.5 Clinical features of metastatic cancer – a retrospective cohort study with nested case control [PIAG 1-05(f)/2008]

The Advisory Group considered this application from the University of Oxford to extract clinical symptoms, signs and investigations from GP records of patients who had died from metastatic cancer. The aim of the research was to obtain information, which would inform clinicians about the presentation of metastatic cancer and so allow earlier diagnosis.

This application was not approved at the meeting. The Advisory Group requested that the application be resubmitted to the next meeting, providing clarification of the following points:

- How soon after death, would the case notes be reviewed? GP practices surrender records of patients soon after their death, and so may not hold the records that are required. If patient notes are no longer with GP practices how patients would be identified in order for notes to be accessed.
- In addition to this, members were not convinced that asking staff to anonymise case notes was too much of a burden for the number of case notes that need to be reviewed. Members requested further evidence of this.

ACTION: The Secretariat to advise the applicant of the Group's decision.

7.6 National General Practice Study of Epilepsy NGPSE [PIAG 1-05(g)/2008]

The Advisory Group considered this application and did not approve the application at the meeting. One of the key principles the Advisory Group has established is that long-term retention of identifiable information should only be done with consent. The Group made clear that GPs were not able to give consent on behalf of their patients. The Advisory Group noted that the applicant was intending to contact patients' GPs and this presented an opportunity for the GP to publicise the study and to attempt to obtain consent. As mentioned in the application, there are a number of support groups for people with epilepsy. Members felt that these groups could also be utilised to promote the work of this research Register.

Members also noted that, Section (r), regarding complying with the Data Protection Act, was not completed.

ACTION: The Secretariat to advise the applicant of the Group's decision.

7.7 Investigating the relationship between Tumour Biology and genetic and environmental risk factors for colorectal cancer [PIAG 1-05(h)/2008]

The Advisory Group considered this application. Members felt that Section 251 was not appropriate for this project. Members felt that this application contained two separate areas of study and that this needed two applications to be submitted to separate out the different aspects. Members also felt that the cancer registries could undertake the work proposed. As this was an epidemiology study, the Cancer Registries could identify the cohort and write to GPs to obtain consent for this cohort. The fact that there appears to be a reasonable alternative in using the Cancer Registries would suggest that Section 251 support is not appropriate for this study.

ACTION: The Secretariat to advise the applicant of the Group's decision.

7.8 Investigation of a possible association between Chromosome 2q terminal deletions and Wilms Tumour [PIAG 1-05(i)/2008]

The Advisory Group considered this application to link information from two databases – the Chromosome Abnormality Database (CAD) and the National registry of Childhood Tumours (NCRT) in order to investigate the possible association between Chromosome 2q terminal deletions and Wilms Tumour. Identifiers were required to facilitate linkage, and would be removed within a 6 month period. The application was approved subject to PIAG's standard conditions of approval.

ACTION: The Secretariat to advise the applicant of the Group's decision.

7.9 Patient characteristics and staff perceptions in two Secure Learning Disability Units [PIAG 1-05(j)/2008]

The Advisory Group considered this application and did not approve the application. Members re-iterated that support under Section 251 of the NHS Act is applicable only where no other reasonable alternative exists. The Advisory Group agreed that in general, issues of resources and time were not sufficient arguments on their own, to set aside the duty of confidentiality. Moreover, that the Advisory Group was unwilling to provide support under Section 251 for issues that could and should have been addressed in the planning of a project. This would appear to be the case with this study. Members felt that anonymising patients' notes was a reasonable alternative to Section 251 support in this instance and that much of the information needed could be obtained from referral notes. This would minimise the resource and time issues for this project.

ACTION: The Secretariat to advise the applicant of the Group's decision.

7.10 Assisted eating and drinking in the care of people with profound and multiple disabilities: the social significance of clinical interventions for managing dysphagia [PIAG 1-05(k)/2008]

The Advisory Group considered this application for Section 251 support for a study to establish the prevalence and need of assisted eating and drinking for people with profound and multiple disabilities, in specific geographic locations. This is part of a larger study investigating how partnerships between all parties involved, i.e. clinical practice, social care are established and maintained to provide best patient care.

The application was approved subject to clarification of the following:

- How the applicant planned to identify the study group for this project.
- The study population and what is meant by profound or multiple disabilities, e.g. will this include the elderly, those with Alzheimer's etc.

Members also indicated that Section (r) of the application would need to be completed.

ACTION: The Secretariat to advise the applicant of the Group's decision.

8. UK Biobank annual review of Section 60 support – [PIAG 1-06/2008]

This was the first annual review submitted by UK Biobank and covered the period up to October 2007. The report illustrated a 10% rate of participation in response to nearly 600,000 invitations. It also included a breakdown of enquiries and complaints and an analysis of reasons given for not participating. This included approximately 400 complaints.

The Advisory Group approved this annual review subject to the following conditions – that in the letter to GPs that UK Biobank requests that GPs both refer complainants to UK Biobank directly and notify UK Biobank themselves of complaints with respect to the use of their personal data for this purpose.

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

9. Future meetings for 2008

April - Monday 14th 2008

June - Wednesday 25th 2008

September - Tuesday 9th 2008

October - Monday 20th 2008

December - Monday 8th 2008

All meetings to take place at the Kings Fund, 11-13 Cavendish Sq, London.