Minutes

PIAG
Patient Information Advisory Group

Meeting held on Tuesday 14th March 2006 at 9.00 am

Present:

Members: Professor Joan Higgins (Chair), Professor Mike Catchpole, Dr Tricia Cresswell, Dr Fiona Douglas, Mr Michael Hake, Ms Ros Levenson, Ms Barbara Meredith, Professor Roy McClelland, Dr Michael Wilks.

In attendance: Mr Patrick Coyle, Ms Melanie Kingston, Mr Sean Kirwan, Ms Karen Thomson.

1. Apologies for absence

1.1 Apologies were received from Ms Stephanie Ellis, Professor Sir Denis Pereira-Gray and Dr Peter Rutherford.

2. Minutes of last meeting

2.1 Minutes of the previous meeting held on the 5 December 2005 were agreed to be an accurate record.

3. Matters Arising/Action Points

3.1 It was noted that a brief report on the Away day would be circulated with the minutes. Actions from the last meeting had been completed other than where indicated in the Secretariat report.

4. Secretariat Report

4.1 The Secretariat report was received and its contents noted.

4.2 <u>National Joint Register</u>

This application from AEA Technology (Momenta) was approved by the Advisory Group at the last meeting. It was reported that the term of the contract was now due for renewal and the DH commissioning team was considering a number of suppliers. The Advisory Group had been asked by the commissioning team to consider whether the Section 60 support could be transferred across to a new supplier, should a change occur, or whether a new application would be necessary.

The Advisory Group agreed that, should a new supplier be chosen, a new application for Section 60 would be necessary, to ensure that there were appropriate information governance and security arrangements in place and that the new supplier took ownership of their responsibilities under Section 60.

Action – Secretariat to inform the Commissioning team

It was noted that a letter had been sent to Sir Nigel Crisp regarding the variance in consent rates among different Trusts, as agreed at the previous meeting. It was noted that a response was still awaited.

4.3 National Patient Safety Agency

Ms Thomson informed the Advisory Group that the Secretariat had been having discussions with the NPSA in relation to their incident reporting systems and whether an application for Section 60 support was necessary. Local organisations maintain incident-reporting databases including identifiers for local management of complaints, and this data is anonymised by Trusts before being sent to the NPSA. However, the anonymisation is not always effective and occasionally either full or partial name is included inadvertently in the free text areas. The Advisory Group confirmed that Section 60 was not necessary, as the NPSA was only seeking anonymised information and were not acting as agents of Trusts to anonymise the data. The Advisory Group welcomed the work undertaken with Trusts by the NPSA to improve their practices and ensure that only fully anonymised data is disclosed.

4.4 Childhood Obesity Project

There have been ongoing discussions with Mr Mike Koudra at the DH Obesity team, with a view to considering future development and in particular what is feasible for data collection this year. The Obesity team still want to obtain patient level data for this year because of pressure being brought to bear from the Department for Education and Skills. It has been proposed to hold this in a national database at the Department of Health (within the UNIFY system). PIAG's advice has been that the data should be collected and held locally in line with other health surveillance activities. The BMI should be calculated locally to an agreed national methodology in relation to date of measurement and date of birth and anonymised (aggregate) data submitted nationally. It was still unclear to the Advisory Group what, if any, added benefit there would be to collecting the data at a national level. Neither was it clear whether this would be sufficient to outweigh the public interest in maintaining patient confidentiality. If there was still a requirement for patient level identifiable data then a Section 60 application would be required. It was noted that although data collection would need to occur in June, there would still be time before the data needed to be submitted nationally in September in order to address these issues at the next meeting provided a Section 60 application was made.

Action – Secretariat to inform Mr Koudra.

4.5 BPSU

Members were advised that the BPSU had requested a nominee to join their sub group committee to look at the issues raised by PIAG. Dr Cresswell had volunteered to undertake this. The Advisory Group agreed her nomination.

Action – Secretariat to inform the BPSU

4.6 UK Caldicott Guardians Council

Members were advised that the UK Caldicott Guardians Council had requested two lay PIAG members to attend Council meetings. Owing to other work commitments, none of the other lay members of PIAG felt able to undertake this additional responsibility at this time. The Chair advised the she was happy to attend a meeting of the Council and give a presentation if that was requested.

Action – Secretariat to inform the UK Caldicott Guardians Council Secretariat

4.7 INVOLVE Conference - September 2006

After the last meeting Ms Levenson had suggested that the Advisory Group should consider participating in the INVOLVE conference in September. The deadline for submissions to participate formally in this conference was in February. The Secretariat was exploring with the INVOLVE Conference team other ways in which the Advisory Group might contribute such as inputting to a themed session.

5. Chair's Report

The Chair informed the Advisory Group that she had nothing further to report following the Away day.

6. Applications previously considered

6.1 UCL -Prognosis of Coronary Heart Diseased in different South Asian populations in Britain [PIAG 3-07(g)/2005]

The Advisory Group considered this re-submission for Section 60 support and agreed that the applicant had addressed the issues of concern raised previously. Members were particularly pleased with the applicant's response on user involvement. The Advisory Group approved the application.

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

6.2 The Vascular Society – National Vascular database [PIAG 4-05(f)/2005]

The Advisory Group were unable to approve this application at the last meeting. The applicants were advised to consider the possibility of obtaining consent from patients prospectively. The applicants had submitted a revised application for this meeting, but had then decided to withdraw their application from this meeting. The Advisory Group discussed the issues related to this application with a view to providing further advice to the applicant about how seeking consent might be appropriately undertaken. Members also felt that whilst for the majority of patients consent should be practicable, that Section 60 may be applicable where procedures have been undertaken in an emergency, or where the patient died or lost capacity prior to consent being sought.

Action – Secretariat to inform the Vascular Society of the additional advice given

7. Applications for Section 60 support

7.1 CFSMS - Measure of 'Health Tourism' in NHS primary care [PIAG 1-05(b)/2006]

The Advisory group considered an application from the Counter Fraud and Security Management Service to measure the levels of 'Health Tourism' in Primary care. The Advisory Group recognised the importance of identifying and countering fraud in the NHS, however it had a number of serious concerns with the application. In the first instance, it was unclear why it would not be feasible for PCTs to provide the information required by the applicants in an anonymised format. PCTs already undertake this type of research and it was unclear what additional value there would be in undertaking this at a national level.

It was noted that the application referred to a similar activity already being undertaken in secondary care, it was unclear if this was being approached in the same way, or if

acute Trusts were undertaking the work and submitting anonymised data. The Secretariat was asked to seek clarification on this.

It was apparent that there were two stages to the research process, the initial identification of a sample and matching the data with immigration data to clarify residency status. Again, it was unclear why PCTs could not undertake the initial sampling to the CFSMS's required methodology. The application asserts that clinical data will not be required but only financial data. If the purpose is to identify the scale of fraud in the NHS, it is unclear how this would be achieved without access to clinical data. Clinical information would be needed to validate whether or not the treatment received was urgent treatment and therefore legitimate or elective and therefore potentially fraudulent.

There was also no consideration given in the application to differentiating between elective treatment and primary care. There are significant public health concerns in relation to primary care, which must take precedence e.g. people not being afraid to come forward and be treated for TB. Undermining confidentiality in this way could have huge consequences for public health.

The Advisory Group further agreed that this was a sensitive issue and that the CFSMS should be undertaking user involvement with appropriate groups e.g. representing refugees and asylum seekers. Members were also concerned that this activity could be undertaken in a way that was discriminatory and advised that the views of the Commission for Racial Equality should be sought.

In light of the above concerns the Advisory Group were unable to approve the application at the meeting.

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

The Chair to write to Richard Douglas and Chris Cockell

7.2 Dr Foster – Disclosure of NHS number to NHS commissioning bodies [PIAG 1-05(c)/2006]

The Dr Foster Unit at Imperial College currently have Section 60 support to hold patient identifiable data and to generate aggregate analyses from these data. The Advisory Group considered an application from Dr Foster to allow them to release the NHS number to local NHS organisations to enable the organisations to link the web-based analyses of aggregate data to locally held patient records.

The Advisory Group had some concerns with the application, in particular that the original application from 2002 stated that Dr Foster would be holding identifiable data for 3 years, which was now coming to an end and this new application would need to extend the time period of the original application.

Concern was expressed about how the disclosure to Trusts would be managed and policed to ensure that only legitimate organisations would gain access and that they would be limited to accessing data about their own patients. It was unclear what additional benefit would be afforded by this project, as PCTs would be undertaking this activity locally as well.

It was also noted that there was little detail about what kind of user involvement was undertaken and that this should be clarified and possibly strengthened.

It was noted that the Unit at Imperial College was funded by Dr Foster but that no identifiable data was released by the Unit to Dr Foster Intelligence Ltd.

The Advisory Group were unable to approve the application at this meeting, however they agreed to invite the applicant to attend the next meeting in order to discuss the concerns raised.

ACTION: Applicant to be informed of the Group's decision and be invited to attend the next meeting.

7.3 NatCanSat – Patient travel times analysis [PIAG 1-05(d)/2006]

The Advisory Group considered an application for a geographical extension to study PIAG 2-07(q)/2004 in order to enable the analysis to cover the proposed new Strategic Health Authority area.

The Advisory Group noted that no user involvement had been sought and agreed that this should be addressed and strengthened all round in relation to their other applications as well. They agreed to approve the application subject to this condition as identifiable data was only required for a limited period.

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

7.4 CRUK and Imperial College – Frequency of follow up for patients with intermediate grade adenomas [PIAG 1-05(e)/2006]

The Advisory Group considered an application from Cancer Research UK and the Imperial College, London to allow record linkage and data analysis of several large datasets collected in screening trials and from hospital endoscopy datasets. The study was in three parts – (1) statistical analysis, (2) psychological analysis and (3) economic analysis.

The Advisory Group felt that sections (2) and (3) of the study were unclear and required further clarification as to how these would be carried out, for example whether patients were going to be contacted for the psychological analysis and whether additional information was going to be collected that had not been mentioned in the application.

The Advisory Group also noted that the applicant's response to involving users in the project was poor, and seemed to lack understanding of the purpose of involving users. It was noted that this section was weak in a number of Cancer Research UK (CRUK) sponsored applications. It was agreed that in addition to asking the applicant to address this, that this should be pursued through CRUK. The Chair agreed to raise this issue with Professor Alex Markham.

The Advisory Group were unable to approve the application at the meeting, because of the lack of clarity about the second and third stages. It was agreed, however, that provided there were no additional major issues following this clarification the Group was content for the application to be approved under Chair's action.

ACTION: Secretariat to inform the applicants of the Group's decision and seek the necessary clarification.

The Chair to arrange a meeting with Professor Alex Markham , Chief Executive of Cancer Research UK

7.5 University of Bristol – Extension of ProtecT Trial [PIAG 1-05(f)/2006]

The Advisory Group considered an application from the University of Bristol for an extension to their ProtecT treatment trial evaluating the effectiveness and cost effectiveness of population based screening for prostate cancer, to allow a medical case note review without consent where men have died. It was noted that for living patients, consent would be sought.

The Advisory Group was impressed with the overall quality of the application; however members were disappointed that section (p) regarding user involvement was weak. Members of the Group felt that at all stages of this long-term study, the researchers should be consulting a standing advisory group of patients, both those with prostate cancer and those at risk of prostate cancer, to seek their views. It was noted that as this is a very long-term study there is a need for ongoing monitoring of the project's management and updating of data security arrangements. It was agreed that the Group should develop a mechanism for application amendments similar to the REC process.

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

- That Section 60 is only to be utilised for access to deceased patients' records where consent has not been sought prior to death, or
- Where consent was sought but no response was received, subject to the communication to treating clinicians requesting access to the data including the following proviso: that where patients had concerns over the use of their data or where the clinician considers that the patient's non-response was passive dissent, that data should not be disclosed in this instance. Where the views of the patient are unknown, to ask clinicians, where it is practicable and appropriate, to seek the views of family members as to what the wishes of the patient would have been.
- That the research team undertake user involvement activities with a relevant group of patients.

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

Secretariat to develop an application amendment process.

7.6 MAGPAS – The Cambridgeshire Trauma Audit and Research Project (CTARP) [PIAG 1-05(g)/2006]

The Advisory Group considered an application from MAGPAS who required Section 60 support to develop a multi-agency population based injury research register. The Advisory Group had concerns with sections (p) and (q) of the application form relating to user involvement and patient information leaflets. The applicant stated that there is essentially no opt out mechanism for this study 'because as with cancer registries, NCEPOD and the other injury research registers approved by PIAG, missing patients compromise the accuracy and meaning of the results'. Members were concerned by the inaccuracy of this statement. PIAG's view is that if patients dissent to having their information used for such secondary purposes then this must be respected. This is also true for Cancer Registries, NCEPOD and any activity undertaken with Section 60 support. In most instances, this is unlikely to have a significant adverse effect on data quality. Occasionally where very small numbers are

involved it is possible; indeed this has been used as a supporting reason for seeking Section 60 support rather than consent, however it does not obviate individuals' rights to dissent.

The Advisory Group also felt that the reasons for not involving users in the study were weak and suggested that the applicants could contact organisations such as Headway as a method of involving users and that it was better to work with one or two organisations than none.

The Advisory Group agreed to approve the application subject to the applicants taking steps to improve their user involvement and amending information materials to include details of how to opt out. Approval was also subject to satisfactory security arrangements.

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

7.7 University of Sheffield – Relationship between Tissue factor and angiogenesis in human colorectal cancer [PIAG 1-05(h)/2006]

The Advisory Group considered an application from the University of Sheffield Medical School for a follow up study from a previous investigation. It was noted that a number of queries had been raised with the applicant including whether it was feasible for the Cancer Registry to undertake the linkage but that no response had been received yet.

The issue of causing distress to patients who may be seriously ill or to their families was discussed as this arises frequently in applications. The Advisory Group believes that patients generally feel positive about being involved in research and that at a time when they may have little control over their illness or other aspects of their lives, being asked to participate in research can be a good experience.

Difficulties may arise from some practitioners not being able to communicate effectively or reluctant to seek consent because of their own discomfort with terminal illness. Concern about distressing patients as a reason not to seek consent is generally of dubious validity. The Advisory Group felt that this was an area where further training would be beneficial and also that they would welcome further research in this area.

The Advisory Group agreed to approve the application if it was not feasible for the Cancer Registry to undertake the linkage and provide an anonymised dataset. The reasons for approval were that:

- even though this was dealing with small numbers and it would be practicable to seek consent from surviving patients who had the capacity to give consent; that it was in keeping with the original research project for which consent had already been obtained.
- Because the researcher already had access to identified information and the linkage would not be rendering the information any more identifiable, than that which had already been obtained. Additionally, the dataset would be significantly less identifiable after linkage was completed.

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

7.8 Royal Marsden Hospital – MRI Impact Study [PIAG 1-05(i)/2006]

The Advisory Group considered an application from the Royal Marsden Hospital to assess whether the single network experience is feasible and reproducible in a national setting. There are two parts to this study, a prospective part, which will use fully anonymised information and a retrospective part that requires Section 60 support.

The Advisory Group were content to approve the application as only minimal identifiers were required and for a short period. The Advisory Group was pleased at the efforts made to minimise the identifiers used. It was noted that there had been no user involvement, and agreed that this should be a condition of approval along with confirmation that satisfactory security arrangements were in place.

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

7.9 St George's University – Prognosis in palliative care study [PIAG 1-05(j)/2006]

The Advisory Group considered an application from St George's Hospital, University of London, which required Section 60 support to develop a novel prognostic index to estimate survival times of patients with advanced cancers. The applicants will seek consent where patients are considered competent and Section 60 will be utilised where patients lack capacity.

The Advisory Group noted that section (o) relating to patients lacking capacity could be clearer. The Group agreed to approve the application on the basis that excluding patients lacking capacity would create data bias and efforts were being made to meet the requirements of the Mental Capacity Act with regard to consent. The approval was subject to confirmation of appropriate security arrangements, the timely reduction/removal of identifiers and that the patient information materials should make it clear that postcode and date of birth would be collected.

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

7.10 ICCH – Differences in Ischemic stroke subtype incidence and risk factors in people of European and Bangladeshi descent living in the UK [PIAG 1-05(k)/2006]

The Advisory Group considered an application from the International Centre for Circulatory Health who required Section 60 support to undertake a retrospective case note analysis of 470 people.

The Advisory Group had some concerns with the wording of the application; in particular, the references to white/British/European were confusing. The application did not clarify how people of Bangladeshi origin would be identified. The Advisory Group questioned whether obtaining consent from 470 could be considered too much of a burden. It was also noted that there was no user involvement. Concern was expressed that the numbers involved might mean that the study was underpowered. It was suggested that a prospective study, undertaken with consent might be more useful.

The Advisory Group agreed that they were willing to provide Section 60 support to allow the applicant to review the case notes in order to identify patients who fit the eligibility criteria and attempt to obtain consent from those patients. Section 60 support was also granted to access the information of deceased patients. The Advisory

Group also agreed that, should the applicants encounter problems in obtaining consent then they could reapply for Section 60 and the Group would reconsider its decision.

The above limited approval was given with the following conditions and with the proviso that the applicant considers the above issues:

-That user involvement is undertaken e.g. with Age Concern Tower Hamlets. It is likely that if engaged, community groups would be willing to champion the research.

-That appropriate information security arrangements are in place.

ACTION: Secretariat to inform the applicants of the Group's decision and seek re-assurance that the issues outlined had or would be considered.

7.11 LSHTM – Research into injury and the links with deprivation [PIAG 1-05(l)/2006]

The Advisory Group considered an application from London School of Hygiene and Tropical Medicine who required Section 60 support to produce maps of hospital admissions for injury and conduct analyses to explore the relationship between injury and deprivation. It was unclear whether soundex coding would be feasible and it was agreed to suggest this to the applicant for consideration.

The Advisory Group approved the application as geographical identifiers were needed for analysis purposes, and because the data would be anonymised within 12 months.

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

7.12 MHAC – Count Me In 2006 [PIAG 1-05(m)/2006]

The Advisory Group considered an application from MHAC to repeat the National Mental Health and Learning Disability Census for 2006 in England and Wales. The applicants had requested to vary the data items collected, including additional and further sensitive data such as sexual orientation. Consequently, the applicant had been asked to submit a full application. The Advisory Group agreed that the questions raised in the previous meeting had been answered sufficiently, and approved the application subject to the reduction of postcode to district level once deprivation scoring allocated and continued user involvement.

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

7.13 HFEA – A population based record linkage study of congenital anomaly and childhood cancer among children born after reproductive assistance (ART) [PIAG 1-05(n)/2006]

The Advisory Group considered an application from the Human Fertilisation and Embryology Authority who required Section 60 support to enable the linkage of three databases. It was noted that there were legal constraints on what data the HFEA could hold and disclose.

Dr Douglas highlighted that there was concern within the genetics community that assisted reproductive technologies can be problematic but that there was a lack of evidence at present, in part at least owing to the restrictions on the HFEA. The Advisory Group noted that there was no user involvement in the project and as there could be implications for patients and members felt that it was vital this was

addressed. It was noted that there seemed to be a misunderstanding about user involvement, that it was not necessary to consult patients directly from the relevant cohort but could be other patients with similar circumstances/conditions. For this study, a group of young people with cancer or genetic conditions would be appropriate. Members suggested that the Teenage Cancer Trust and Contact a family would be useful groups to approach.

The Advisory Group approved the application subject to improved user involvement. Additionally it was proposed that if the need should arise again to conduct such linkage activities, the HFEA should make a generic application to cover all such projects. The HFEA would themselves require that only anonymised data would be disclosed to researchers and that any identifiers already held would be destroyed so that linkage across databases would not be feasible and this provided the necessary assurance to the Group that such linkage activities would be conducted in line with PIAG requirements.

ACTION: Secretariat to inform the applicants of the Group's decision and suggest that a generic application is made.

8. Update on the Secondary Uses Service

The Chair welcomed Jeremy Thorp and Wally Gowing from the Secondary Uses Service (SUS) at NHS Connecting for Health who gave a presentation on the implementation of the SUS, covering its development, architecture, timescales, access controls, and pseudonymisation goals. The Advisory Group received the NHS CFH document *'A framework for SUS Information Governance*' [PIAG 1-06/2006] and noted its contents.

It was apparent that in the short term there are issues in relation to transition, which are likely to mean an increase in access to identifiable data. It was acknowledged that in the short term there was a need to provide evidence that validated quality data would be available through SUS in order to obviate the need for use of other sources of data. Currently identifiers are often required in order to validate and link data from a range of sources, in time the SUS will facilitate this linkage without the need for identifiable data to be disclosed. It was noted too that often postcode is needed in order to allocate deprivation scoring, or to calculate distances, and to cope with NHS and local authority boundary changes. SUS will have access to postcode data and will be able in due course, to facilitate such analyses without the need for identifiable data to be disclosed in the short to medium term however, this will not be possible and there will continue to be a need for disclosure of identifiers with consent or Section 60 support.

There was a discussion about the need for Section 60 support both, for the receipt and holding of patient identifiable data by SUS, and for access to and disclosure from the SUS. It is likely that there will need to be a series of applications to address the changing circumstances and in the first instance Section 60 will be needed to provide a lawful basis for data to be held in the SUS.

It was noted that a sub-group of the Care Record Development Board (CRDB) was being set up as a short-life group to consider Research and the use of the Care Record in response to the AMS report on the use of patient information in research.

It was agreed that an application for Section 60 support would be submitted to the June meeting.

9. Independent Sector Issues

9.1 The Advisory Group considered a draft briefing on issues related to the independent sector. It was reported that a ministerial briefing was being prepared on independent sector offshore processing issues. It was agreed that a small group should take this work forward and the following members undertook to be part of this group: Ms Levenson, Ms Meredith and Dr Wilks. Dr Douglas agreed to comment on issues relevant for the genetics community. Members undertook to email further examples of issues to the Secretariat. It was also agreed that this issue should be included in the response to Mr Jeremy Thorp in relation to the development of SUS.

Action – All members to identify and email other examples.

Secretariat to convene the working group.

10. Any Other Business

10.1 ONS issues

Professor Catchpole raised an issue, which had arisen for the Advisory Group for Medical Research (AGMR) at the ONS who handle the applications for Section 60 support for flagging and tracing of patients. The key issue was about the legitimacy of providing Section 60 support where there was evidence of significant rates of dissent. An application had come to the AGMR for flagging a cohort of serving and former soldiers who had served in the Gulf. There was evidence that as many as ten per cent had or were likely to dissent. It was agreed that in the first instances this should be pursued through a meeting with ONS AGMR representatives. The Chair, Professor Catchpole and Ms Thomson would attend for the Advisory Group.

Action – Secretariat to convene a meeting with representatives of the ONS AGMR.

10.2 Draft approval template

Ms Meredith had produced and circulated a draft application approval template as agreed at the previous meeting. The Group was asked for their comments on the document. It was agreed that the Advisory Group would trial using the template at the next meeting. It was agreed that this should not be used or perceived as a scoring sheet but a means of recording views picking out key issues.

Action – All members to comment on the draft template.

Secretariat to circulate blank approval template forms for the next meeting.

11. Future meetings for 2006

Tuesday 13 June 2006

Monday 11 September 2006

Wednesday 13 December 2006