Minutes

PIAG
Patient Information Advisory Group

Meeting held on Wednesday 12 September 2007

Present:

Members: Professor Dame Joan Higgins (Chair), Dr Tricia Cresswell, 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: Miss Anoopa Bharath (Secretariat), Dr Patrick Coyle (SCAG), Ms Melanie Kingston (Secretariat), Mr Sean Kirwan (DHIPU), and Ms Karen Thomson (Secretariat), Mr John Sheehan (Secretariat).

Visitors in attendance for the relevant part of the agenda: Professor Jan Van Der Meulen, Ms Lyn Copley (to discuss the CRANE application).

1. Welcome and Apologies for absence

1.1 Apologies for absence were received from Professor Mike Catchpole & Dr Fiona Douglas. Apologies were also received from Dr Wilks who was only able to stay for the first part of the meeting to discuss the GPPE Survey and Professor McClelland who had to leave at 1pm.

2. Minutes of last meeting

2.1 Minutes of the previous meeting held on 12 June 2007 [PIAG 3-02/2007] 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 Mental Capacity Act 2005

It was noted that aspects of the Mental Capacity Act 2005 (MCA) were relevant to PIAG's deliberations and that the loss, or potential loss, of capacity needs to be addressed in some types of Section 60[1] applications. Researchers need to take into account the capacity of patients to consent to participating in research. Obtaining consent from patients should anticipate the loss of capacity to ensure that the consent remains valid beyond the loss of capacity to be in line with the provisions of the MCA. The principle that patients lacking capacity should not be treated less favourably than those with capacity, means that lack of capacity is no longer a justification for using S60 powers. There may be other reasons, however, why consent or the assent of relatives, or donees is not practicable, which would justify use of the powers with respect to research involving people lacking capacity.

[1] Section 60 of the Health and Social Care Act 2001 was re-enacted under Section 251 of the NHS Act 2006.

For established research, where the consent did not anticipate the loss of capacity, the following are options to address this:

1) Where there is contact between the researchers and the patients, it is practicable for renewed consent to be sought, which anticipates the loss of capacity. This is the most suitable option for long-term studies.

2) Where the patient has lost capacity, the provisions of the MCA would apply and the researcher should consult with family members or the relevant nominated individual.

3) Where there is no contact with patients, at the point researchers are informed of the loss of capacity, researchers have the choice of retaining data already collected but not collect any new data. Alternatively, where they are able to pseudonymise the data effectively, researchers can continue to receive new data in pseudonymised form, provided that all the data obtained has been effectively pseudonymised, so that the researcher has no access to the identity of individuals such that the data would no longer constitute personal data. The trusts providing the data could hold the key to enable linkage. The Advisory Group agreed it was reasonable to process the data in order to remove identifiers and that this did not require approval under Section 60.

3.2 IT systems testing and maintenance

The Secretariat reported that there had been an enquiry with respect to the legitimacy of Information Management & Technology staff having access to patient identifiable data in order to test new IT systems, prior to and shortly after becoming operational. It was noted that current Departmental guidance was that synthetic data should be used wherever possible and consent for a minimal number of records sought where identifiable data was needed. Additionally, the question has also been raised about when access to identifiable data is necessary to maintain operational systems. In the main, such testing and maintenance would not require access to identifiable data. Members felt there was a distinction to be made between testing of new systems and maintenance of operational systems and felt that the underlying principle must be that access to identifiable data should only be permitted when strictly necessary and robust justification provided. For testing of new systems, synthetic data should be used wherever possible. The Advisory Group agreed that there was a strong public interest and patient safety requirement for operational systems to be effectively maintained and therefore that restricted access to identifiable data when necessary to support such maintenance work was legitimate and did not require further approval. This is provided there were robust Information Governance safeguards in place e.g. good contractual obligations of confidentiality and a clear data destruction policy and implementation plan. Similarly, data controllers need to maintain a register of access for all contractors.

Members understood the need for systems testing prior to launching new systems, and in the early days after launch, to ensure they were working as anticipated and designed. Members felt, however, that this was more problematic as this use of sensitive personal health information was not directly supporting the care of patients and ordinarily would require consent.

It was noted that there were similarities with the banking world but members agreed this was different, in that people entered into a formal contract with a bank which would include the processing of data for these and a range of other purposes. This is not the case with respect to the NHS, which has no formal contract with patients and the use of personal data for secondary purposes is opaque.

Members noted that the DH guidance had been that consent should be sought from a small cohort of patients where real rather than synthetic data was required. Members agreed to keep a watching brief on this issue.

3.3 CRDB Secondary Uses Report

It was noted that the Care Record Development Board report: "*Report of the Care Record Development Board Working Group on the Secondary Uses of Patient Information*" had been published. The Advisory Group welcomed the report overall but members also indicated that they felt the Advisory Group should have been more involved in the development of the report, as there were a few key confidentiality issues which were problematic and about which members felt that the Advisory Group could have advised. The two main issues were the legal basis for disclosure of confidential patient information to the proposed Safe Havens and a lack of sufficient clarity in the language, which resulted in confusion over the legal requirements for valid consent and when explicit consent was required.

Members agreed that a response should be drafted outlining the Advisory Group's concerns.

Action: Secretariat to draft a response and to send it to Harry Cayton, as Chair of the NIGB.

3.4 NHS Central Register and ONS

It was reported that the NHS Central Register would be moving from the Office of National Statistics (ONS) to the Information Centre for Health and Social Care (IC) in April 2008. Additionally, it was noted that following the Statistics and Registration Services Act that the functions of the General Registrar's Office were being separated from the Statistics and Registration Board (formerly the ONS) and that plans were in hand to develop Memoranda of Understanding between the relevant bodies to facilitate appropriate data-sharing. It was reported that there are no plans to alter the ONS policy that requests for access to data by external bodies are referred to the supplier of the data.

These changes have implications for the work of PIAG as the ONS Advisory Group for Medical Research (AGMR) was established at the behest of PIAG to review the flags held on the NHS Central Register in September 2002 and to consider new applications for flagging. The AGMR was given delegated authority by PIAG to permit the use of Section 60 powers for flagging studies, provided that was the only aspect of the study that required Section 60 support. The above changes will mean that the AGMR will cease to exist and members were asked for views on how the work undertaken by AGMR should be handled in the future. It was noted that PIAG does not currently have expertise in Registration law and issues.

It was noted that the Chair and Secretariat were to attend the final meeting of the AGMR to discuss future arrangements.

3.5 UKCRN

It was reported that the Secretariat had received several reports that the UKCRN had been issuing guidance that research network staff were to be regarded as part of the 'Clinical care team' and consequently that there was a legitimate basis for such staff to access patient records without consent. Whilst there is no formal definition of the 'Clinical care team', it should be self-evident that the clinical care team consist of staff directly involved in the patient's care. The clinical care team have legitimate access to patient's confidential information through consent implied as part of consent to treatment and examination. Researchers and research support staff are outwith the clinical care team and therefore there is no basis for implying consent for them to access confidential patient information without explicit patient consent.

It was noted that the Secretariat had raised this as an issue with UKCRN; members agreed however that this should be raised as an issue with the Department of Health's Research and Development team. It was also agreed that there is a need to work with UKCRN on agreed processes for obtaining consent for researchers and research support staff.

Action: The Chair to write to Marc Taylor at the DH & the Secretariat to pursue the facilitation of consent with UKCRN

3.6 Using Section 60 to require processing

It was reported that a question had been raised on more than one occasion about the extent of the Section 60 powers and whether it was solely permissive or if they could be used to require the processing of confidential patient information. It was noted the legislation refers to 'requiring' the processing of information. It was noted that Section 60 had not been used to require processing but had only been used to permit disclosures. It was noted that if processing were required this would have two outcomes:

- It would mean that patient's withholding of consent to use identifiable information would be over-ridden.
- It would override clinicians' refusal to disclose identifiable information.

It was further noted that the powers to require the disclosure of information would need to be balanced against other legal powers. Using Section 60 powers to require processing may be contrary to the requirements of the Human Rights Act that a judgement be made in relation to each individual to ensure that the disclosure was proportionate.

It has long been a principle of the Advisory Group that Section 60 should be not used to over-ride the dissent of individuals where this has been expressed and appropriately recorded. Members further agreed, however, that whilst Section 60 approval would provide a secure legal basis for disclosure it should not be used to over-ride a clinician's refusal to disclose identifiable data. In general, therefore Section 60 powers should be regarded as permissive rather than mandating disclosure.

3.7 Approval extensions

It was noted that the following extensions had been approved by Chairs action since the meeting in June:

PIAG 1-05(c)/2007 - Linkage of National Cancer registry data to National HES data. The extension for this study was for inclusion of all patients diagnosed with cancer during 1989-2005 aged 0-14 at diagnosis and all patients diagnosed with cancer during 1971-1988 resident in England, aged 0-99 at diagnosis.

PIAG 1-08(a)/2003 - National Cancer Screening Programmes: Bowel cancer screening. This extension was to allow the invitation for screening, the dispatch of screening kits and the sending out of normal results to be outsourced to an independent provider. This was approved subject to an appropriate data processing and confidentiality contract and safeguards being in place.

PIAG 4-06(c)/2006 - Long term sequelae of radiation exposure from computed tomography in children and adolescents. This extension was to include patients up to the age of 22.

3.8 Handling Press Enquiries

Following a press enquiry made to a member, it was noted that all press enquiries for PIAG related business should be handled by the DH press office. If any member were to be approached in future by the press with an enquiry, the member should refer them to the DH Press office and notify the PIAG secretariat.

Action – All members to follow this guidance.

3.9 New Members

It was noted that the advertisements to recruit new members would be published shortly. The Secretariat reported that a timetable for recruitment has been developed with the aim that the new members would be appointed in time to attend the December meeting.

3.10 Consultations

It was reported that responses to both the Counter Fraud and Security Management Service Code of Practice Consultation and the Social Care Record Guarantee consultation have been drafted and circulated to members for comment. It was agreed that final approval of the responses could be undertaken by Chair's action.

3.11 Dr Foster Unit at Imperial Audit

The Secretariat report that NHS CFH had commissioned Ernst & Young to audit the Dr Foster Unit at Imperial as part of an audit of the Secondary Uses Service as this was currently the only external body receiving identifiable data from the Secondary Uses Service. NHS CFH wanted assurance, before issuing a contract to the Dr Foster Unit at Imperial, that there were appropriate security measures in place and that only pseudonymised data would be disclosed to Dr Foster Intelligence. It was noted that the Secretariat had met with staff from Ernst & Young to explain the nature of the approval under S60. The documents relating to the Section 60 approval including

access to the application forms and other correspondence have been made available to Ernst & Young.

4. Chair's Report

4.1 Reappointments

The Chair reminded members that they needed to reapply (via the secretariat) for reappointment to PIAG, if they wished to remain on the Committee.

Action – All members to submit their re-appointment forms to the Secretariat.

4.2 Ways of working

It was noted that the Advisory Group's workload, both for members and the secretariat has been increasing. It was agreed that the workload was likely to continue to increase with issues such as the development of the National Information Governance Board (NIGB), the continued development of the Secondary Uses Service (SUS), and taking on the functions of the Security and Confidentiality Advisory Group (SCAG). Following discussion, it was agreed to extend the number of meetings from four to six each year. It was also agreed that the Fast Track applications should have 12 specific monthly deadline dates.

Action – Secretariat to implement

5 Applications previously considered

5.1 GPPE [PIAG 2-05(c)/2007]

This application was originally considered by the Advisory Group at its meeting in June. The Chair and Dr Wilks met with representatives from the Primary Care team at the Department of Health, Ipsos Mori and Apollo on 3 September in order to discuss the concerns previously raised by PIAG. They reported on the discussions that took place and indicated that the meeting had been broadly reassuring, as efforts had been made to address many of the concerns previously raised by PIAG e.g. the envelopes that would contain the survey would be anonymous in origin and labelled, 'Private: Addressee only'. Additionally, it was recognised that surveys could be an important part of service evaluation and assist with improvements in the delivery of services. It became apparent during deliberation, however, that members continued to have concerns with the proposal.

It was felt that further effort could be made to place the patient at the centre of these plans, and the need to seek consent and engage patients cannot be overlooked. It was also noted that this survey is linked to meeting DH targets and members felt that the letter to be sent to patients was misleading, as it did not mention that the survey was linked to GP payment. Members also felt that the claim that this survey was a random sample of patients did not appear to be accurate. More fundamentally, it was clear that national surveys of this type appear to be a central part of Departmental policy and this raises the question of whether there would be a need for a more permanent

statutory basis for these surveys. If they were to continue to be conducted in this way, they involve a breach of confidence and it was suggested that a different approach should be adopted which would not breach confidentiality.

Members were clear that the information requested by GPPE is confidential and that there was a significant cost in terms of public trust in a confidential service, if this and other such surveys were to continue to be approved. This is a particular concern when it comes to highly sensitive information such as contraception, domestic violence etc. as trust is such a vital component of the clinical relationship.

Members also felt that this underlined the need for a national targeted public information campaign, such as that commissioned by NHS CFH to improve the transparency of data use. However, this campaign has not yet been launched (although there have been local information campaigns in the NHS CFH pilot sites) Members also stated that relying only on posters in GP surgeries and similar information campaigns cannot provide sufficient information to allow an informed decision by patients.

Following considered deliberation the Advisory Group rejected the application for the following reasons:

- Members considered that the public interest justification for this activity was insufficient to over-ride the duty of confidentiality, as there are other approaches that could be taken, which would not involve a breach of confidence. Section 60 support was established, initially on a temporary basis, to provide a lawful basis for disclosure where neither consent nor anonymisation was practicable. It was not intended as a means of sidestepping the duty of confidentiality. It was felt that adopting this approach to national surveys was a matter of convenience rather than necessity for the Department and therefore was regarded as an inappropriate use of Section 60 powers. Moreover the Advisory Group were concerned that this was not the sole application of this type it had received in recent months and were concerned that a precedent would be perceived to be established both for national surveys and other activities for monitoring Department of Health targets.
- Members felt that the sharing of information particularly in relation to such large numbers of patients had consequences and a human cost in terms of public trust in a confidential service. Members wanted to emphasise that they are supportive of service evaluation activities and regard performance management as a legitimate purpose but that the process had to be appropriate.
- Members were concerned about the lack of transparency about the disclosure, both in terms of how the survey would be used to determine payments to GPs and how patients had been selected. Whilst the Advisory Group were supportive of omitting information, which would indicate that patients had been selected because of having had an appointment, to suggest that selection was random was felt to be misleading and therefore disingenuous.
- Given the policy context of increased service evaluation at a national rather than a local level, the Advisory Group felt that work was needed to establish a better

long-term solution, one grounded in consent or statute, and which was well monitored. Advisory Group members expressed a willingness to work with Departmental colleagues to facilitate this. A key component of this would be to provide a proper public information campaign about secondary uses of NHS data. It should be noted that the Advisory Group regards this as essential to meeting data protection fair processing requirements, in terms of informing patients about how their information may be used, but that such a public information campaign is not sufficient to imply consent for secondary uses.

It was also agreed that the Chair should write to the Secretary of State outlining the Advisory Group's concerns, with a copy to Harry Cayton, Chair of the NIGB:

1) Information relating to contact between patients and GPs is confidential and this has raised concerns with PIAG. These concerns are heightened by the fact that survey letters may be sent to 10 million people.
2) There also seems to be a lack of transparency in how people are being selected and how the information is being used.

Action: Secretariat to write to NIGB and Secretary of State regarding the concerns of the Advisory Group.

6. Summary of fast track applications [PIAG 3-05(FT)/2007]

Between the June 2007 and September 2007 meetings, Advisory Group members considered two applications under the fast track process. These are summarised below:

6.1 Intussusception in children aged less than 12 months. [PIAG/BPSU 2- 05(FT1)/2007]

This application from the British Paediatric Surveillance Unit was for a surveillance study to allow the epidemiology of Intussusception in the UK and Ireland to be better understood. The aims of the study were to address the following research questions:

- To determine the incidence of clinically presenting Intussusception in children under 12 months in the UK and Ireland.
- To report its distribution by age, sex and ethnic group.
- To report the clinical features at presentation.
- To report the diagnostic procedures used and outcome of the different management modalities including surgery.
- To report early clinical management and morbidity and mortality post diagnosis.

This application was approved subject to the following conditions:

- Improved user involvement.
- Confirmation of satisfactory security arrangements.

6.2 Evaluation of new models Improving Access to Psychological Therapies [PIAG 2-05(FT2)/2007]

This application was for a study to evaluate the performance of two NHS pilot sites (Doncaster and Newham) providing increased access to Cognitive Behavioural Therapy (CBT) to people suffering with anxiety and depression and being treated in primary care. Each site is being compared to two similar sites where the increased access is not yet available.

This application was approved subject to the following condition:

- Confirmation of satisfactory security arrangements.

7. New applications for Section 60 support.

7.1 Waits for Hospital Treatment Survey [PIAG 3-05(b)/2007]

The Advisory Group considered this application from the Department of Health to use a data processor (Ipsos MORI) to conduct the process of sending out the Wait for Hospital Treatment survey. The primary objective of the survey was to obtain quantitative feedback on patient experiences of hospital referrals, and whether, in each case, the Trusts were meeting the 18-week wait target set by the Department. The initial pilot survey was being conducted in five Trusts, with each individual Trust managing their own sampling and mailing process. This application was to allow Ipsos MORI to manage the mailing process in the hope that this would improve the response rates of the survey particularly in relation to minority populations and reduce the administrative burden on the Trusts.

Use of Section 60 powers is limited to where there is no practical alternative. In this case, the pilot that was originally set up had not relied upon Section 60 support and members wanted more detail on why the pilot methodology was not being used. Furthermore, it was felt that the need to inform patients and the reasons for not seeking consent had not been addressed adequately. As previously indicated, use of posters is not a substitute for consent. It was unclear why letters could not be sent from GPs or from hospitals. Members were concerned that patient involvement was poor. The application was deferred and PIAG will write to the applicant and suggest that they meet with PIAG Secretariat to look for a way forward for this survey.

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

7.2 Disclosure and use of clinical audit data to support National Clinical Audit (NCASP) [PIAG 3-0(c)/2007]

The Advisory Group considered this updated application from the Information Centre for the NCASP programme to cover the migration to new systems. This application was to allow for new systems, which provide improved: analysis and reporting; access controls; security and confidentiality of identifiable information. This application included a request to use patient name, in order to perform linkage with the NHSCR to obtain mortality information. Patient name was not included in the original application for Section 60 support from the Healthcare Commission.

Members considered this application and felt that the use of names was a retrograde step. They also felt that clarity about the deadlines for an exit strategy was needed.

The applicant needs to be clear on whether the exit strategy is consent or anonymisation/pseudonymisation. Currently the Healthcare Commission is the sponsor but this will change to the Department next year. Information security was also an outstanding issue as the contractor is yet to be confirmed and as such, the Information Security arrangements need to be approved by the Department's Security Adviser before any approval could be granted. It was agreed that the applicant should submit a revised application for approval by Chair's action assuming the above concerns can be satisfactorily addressed.

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

7.3 National Clinical Audit Support (NCAS) National Infarct Angioplasty (NIAP) Hip Fracture and Arrhythmia [PIAG 3- 05(d)/2007]

The Advisory Group considered this application for three additional audit programmes aligned with the National Clinical Audit Support Programme (NCASP) infrastructure. These audits do not fall within the Healthcare Commission sponsored NCASP. This application was to cover the National Infarct Angioplasty Project (NIAP), the Hip Fracture audit and the Arrhythmia audit.

This application was submitted by the Information Centre for Health and Social Care. Members felt that separate applications were needed for each audit with an explanation of why consent was not feasible and a clear exit strategy from requiring Section 60 support. It also suggested that the Patient Information Leaflet would benefit from a 'plain English' review. The Advisory Group requested that the Information Centre resubmit a separate application for each of the three audits, covering the above concerns in more detail.

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

7.4 25 year mortality of a community cohort with schizophrenia [PIAG 3-05 (e)/2007]

This application was for a study to measure the mortality rate of a cohort of 370 people with schizophrenia, first identified in 1981, and to examine medical notes in order to identify possible reasons for the higher death rate than the general population.

PIAG considered this application and raised the following issues. NHS Trusts have strict controls over releasing the records of deceased patients to anyone. This is particularly so with mental health records as they often contain third party information about, for example, family members. Members also sought clarification on whether the application related solely to records of deceased patients or also living patients. On the understanding that the application included access to records of living patients, members felt the issue of consent had not been addressed properly.

The Advisory Group did not approve the application and suggested the applicant submit a revised application for the next meeting, clarifying why information on live patients was needed and indicating what consideration had been given to the feasibility of obtaining consent from surviving patients, addressing how information extracted from records would ensure that identifiable third party information was not collected.

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

7.5 Redfern Enquiry into human tissue analysis in the UK nuclear facilities [PIAG 3-05(f)/2007]

Between 1961 and 1992, human tissue and organs were removed from deceased individuals working in the nuclear industry or living in the locality of nuclear sites for the purposes of research or population studies into the effects of radiation. Concerns have been expressed that this was undertaken without consent. The Advisory Group considered this application to allow the Redfern enquiry access to records containing patient information in order to investigate the circumstances surrounding these events and to report to the Secretary of State and make recommendations.

It was noted that members had had the opportunity to consider the Enquiry since the last meeting and had agreed that this was one of those rare circumstances where there is an over-riding public interest justification for access to the information. This was not least because there were sensitivities, which meant it would not always be appropriate to approach families of the deceased to seek their assent. It was further noted that Section 60 powers provide for the common law duty of confidentiality to be lifted. Section 60 approval provides assurance to those responsible for confidential patient information that there is a lawful basis for disclosure not only of confidential patient information held in medical records but anywhere where such data is recorded subject to other legal constraints. It does not apply to other types of personal data, although patient information has a broad definition.

The Enquiry had sought Section 60 approval in order to provide such assurance, to the disclosing body, of the lawfulness of the disclosure. The Advisory Group approved the application subject to the following conditions:

1) The limitations of Section 60 powers are noted and adhered to.
2) That the individual's previously expressed withholding of consent or the refusal of assent by family members is to be respected.
3) That patient data is anonymised prior to archiving.

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

7.6 The British Society for Urogynaecology Audit Tool (BSUG.Net) [PIAG 3-05(g)/2007]

The Advisory Group considered this application from the British Society for Urogynaecology in conjunction with the Royal College of Obstetrics and Gynaecology. The application was for an online database tool, to be used to gather UK based operative data to review trends in patient care.

Following consideration, the Advisory Group rejected the application on the basis that there would be many opportunities for a variety of clinicians to seek and obtain consent and that the reasons given suggesting that seeking consent would be impractical, cannot be substantiated. The application did not provide evidence that any attempt had been made to establish a consent mechanism. If having undertaken

this, the applicant can demonstrate that consent is genuinely not practicable then they are welcome to re-apply.

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

7.7 Long term survivors of adult cancers-the use of primary care services and unmet needs [PIAG 3-05(h)/2007]

The Advisory Group considered this application from the University of Oxford to receive patient information from two cancer registries; this information would then be used to contact relevant patients, via their GP, to seek their consent.

The Advisory Group recommended that as the cancer registries and GP practices already have legitimate access to the data, the cancer registries should be asked to identify the relevant cohort of patients according to the criteria for the study and then provide data direct to the GPs who could send out the invitations. This would obviate the need for Section 60 approval entirely. Two options were identified:

1) The cancer registries could identify patients and produce the letters to patients, sending them to the GP practices to post out once the GPs have filtered for appropriateness.
2) The cancer registries could identify patients and provide a list to each of the GP practices, GPs would check the list and remove anyone it would be inappropriate to approach and then practice staff would produce the letters and send out the packs.

Members were also concerned about the lack of user involvement in this project and asked that this comment be provided to the applicant.

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

7.8 Identification of bowel cancers in the English bowel cancer services screening pilot [PIAG 3-05(i)/2007]

The Advisory Group considered this application from the Institute of Cancer Research for a study to (1) identify interval cancers that occur after a negative screening test result and (2) to identify cases of bowel cancer in non-responders to screening to calculate the incidence in both groups.

Members questioned the justification for the research, as the application had not been sufficiently clear about the link between cancer and screening. Members felt that the question about why consent was not feasible had not been adequately addressed and that patient involvement needed strengthening.

It was agreed that, provided these questions could be answered satisfactorily, the revised application could be re-considered by members before the next meeting and approved by Chair's action.

Action: Secretariat to write to the applicants to inform them of the Advisory Group's decision

7.9 Patterns of clinical practice and outcome among women with breast cancer in England [PIAG 3-05(j)/2007]

The Advisory Group considered this application from The Royal College of Surgeons of England to create a linked HES-Cancer Registry dataset containing diagnosis and treatment information on women with breast cancer in England. The information requested was name of hospital, age at admission to hospital, sex and date of death. This Group agreed that this was minimally identifiable information and approved the application subject to:

- Confirmation of how identifiable data would be further reduced.
- Confirmation of appropriate security arrangements

Action: Secretariat to write to the applicants to inform them of the Advisory Group's decision

7.10 Sun exposure and dietary vitamin D intake as predictors of mortality from melanoma [PIAG 3-05(k)/2007].

The Advisory Group considered this application for a follow up study to flag the vital status of study participants. Participants originally gave consent for the collection and analysis of questionnaire data but not for flagging on the NHS Central Register held by the ONS. Flagging is required to confirm vital status and if deceased, cause of death.

As consent had previously been given, it is likely patients would also have agreed to flagging and therefore, members agreed to approve the application subject to the following conditions:

- Improved user involvement.
- Confirmation of appropriate security arrangements.

Action: Secretariat to write to the applicants to inform them of the Advisory Group's decision

7.11 Audit of the effect of age at the first invitation for breast screening in the NHSBSP in England and Wales [PIAG 3-05(l)/2007]

The Advisory Group considered this application from NHS cancer screening programmes for an audit to establish whether the age at which women are first invited for routine mammogram affects mortality from breast cancer.

The Advisory Group recognised that this was an important question and of clear patient benefit and therefore the Advisory Group approved the application subject to the following conditions:

- Improved user involvement.
- Confirmation of satisfactory security arrangements.

Action: Secretariat to write to the applicants to inform them of the Advisory Group's decision and invite them to a meeting.

7.12 CRANE database [PIAG 3-05(m)/2007]

The Chair welcomed Dr Jan Van der Meulen and Ms Lyn Copley to the meeting, to discuss the CRANE Database. Dr Van der Meulen explained what it was they were trying to do, and answered the members' questions. A key issue related to a lack of clarity in the application about the multiple phases of data collection and purposes for the database. A major concern with the application had been the impression that the applicant was wishing to override patients' dissent. Members made it clear that the Advisory Group differentiated between (i) where it was impractical to seek consent, (ii) where it was unclear whether valid consent had been obtained and (iii) where consent has been withheld.

Members agreed that there was a need to hold a unique identifier in order to prevent bias and duplication in the database and to link data longitudinally. A core issue, which had not been addressed in the application, was how the process of seeking consent was handled where babies had died. Members agreed that this should be addressed in a revised application and submitted for consideration.

The Advisory Group also agreed the following:

- CRANE needs to identify a better process for managing consent where babies had died.
- That there needs to be clear separation between the register and the research database and that CRANE should re-apply for Section 60 approval for the register only.
- The applicant needs to identify the minimum dataset required for epidemiological purposes and seek consent for the research database.

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

7.13 BANS [PIAG 3-05(n)/2007]

PIAG members considered this application. There was concern at what seem to be a lack of understanding of the role of the Advisory Group and the nature of consent and confidentiality. Members acknowledged that some of the issues from the original application had been addressed; there were concerns as to whether this was because of obligation rather than improving the consent and confidentiality process. Members agreed to invite the applicant to meet with the Secretariat to address the following issues:

1) Clarity on understanding of the role of the Advisory Group.
2) Attention to Mental Capacity Act 2005.
3) Improved patient involvement.

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

8. Review Fast Track application process [PIAG 3-06/2007]

It was noted that the Fast Track application process had been used effectively. It has also assisted in reducing the number of applications that would otherwise have been considered at a meeting. It was agreed to extend the categories of applications that can be considered under the fast track process. To facilitate the management of the fast track applications it was agreed to have specific deadlines for submission at the start of each month. The Secretariat will modify the Fast Track Application Process document. It was agreed these amendments could be approved by Chair's action.

Action – Secretariat to revise Fast Track Application Process document.

9. e-Learning for Health – Use of images [PIAG 3-07/2007]

The Advisory Group was asked to consider a policy document from the Department of Health's e-Learning for Health programme on the use of images: *Consent for the electronic use of images for teaching and assessment*. The programme obtains consent for the use of images, but there are issues with respect to historically obtained images. The Advisory Group was asked to endorse the policy and advice was sought on two key issues:

- Current guidance on consent has not addressed two areas of potential image use – use of anonymised images that cannot be accurately dated, and use of investigations such as ECGs and blood results. Approval was requested to process these images without consent.
- Currently archive material, obtained without consent, is excluded from public and patient facing educational material. This can present challenges however where there is difficulty in obtaining new images.

Members welcomed the work undertaken by e-Learning for Health in obtaining consent for the collection and use of images. It was noted that, where consent was not in place, images and data must be anonymised prior to disclosure to DH e-Learning for Health, as otherwise Section 60 approval would be required.

Members felt it was important to separate out the two issues of:

1) Historical (or undated) anonymised images / investigations, which had been obtained without consent.

2) 'internal' use for medical training v 'external' use for public facing materials.

With respect to images that are undated, but fully anonymised, PIAG agreed that these images might be used without consent for the purpose of clinical education and training via the secure limited access website, but that in general they should not be used for public-facing education materials. There was recognition that there may be a few exceptions, e.g. images of small pox are impossible to obtain now and therefore the historical images are all that are available.

Members further agreed that DH e-Learning for Health could process anonymised investigations such as ECGs and blood results without the need to obtain consent. Given that such investigations are data rather than images, they are by nature less likely to be identifiable and may be used for both internal and external use, provided they are effectively anonymised.

The principle with respect to external use of images should be that only images obtained with consent should be used. Members recognised, however, that there are a few exceptions, as indicated above, where new images are difficult or impossible to obtain. Efforts should be made to move to an entirely consent-based library as soon as possible (apart from the rare historical exceptions).

The Advisory Group was broadly supportive of the policy but subject to the following:

1) Where images are to be used in a public facing environment, other than in exceptional circumstances, they should have consent. Great care must be exercised, however, to ensure all images are anonymised very effectively and efforts made to 'future-proof' anonymity. Where there is any doubt, images should not be used in a public facing environment.
2) The Advisory Group asked for an indication of the timescale for the database to become entirely consent-based (other than for those exceptional circumstances where obtaining new images with consent is not feasible).
3) Members also asked to review the security and access arrangements to re-assure itself of the safeguards in place, particularly with respect to highly sensitive images.
4) Access to images needs to be on a restricted level for identifiable data (i.e. only where consent is in place).

10. Annual Report 2006/7 [PIAG 3-09/2007]

Members were asked to email the secretariat any comments regarding the draft version of the Annual Report.

Action – All members to submit comments on the Annual Report.

11. Future meetings for 2007

Tuesday 4th December 2007

It was noted that the dates of meetings for 2008 would be circulated and agreed by email.