Minutes

PIAG
Patient Information Advisory Group

Meeting held on Tuesday 13 June 2006 at 10.30 am

Present:

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

In attendance: Dr Fiona Bisset (Scottish Executive) Ms Melanie Kingston, Mr Sean Kirwan, Ms Karen Thomson.

1. Apologies for absence

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

2. Minutes of last meeting

2.1 Minutes of the previous meeting held on the Tuesday 14 March 2006 were agreed to be an accurate record subject to minor amendments.

3. Matters Arising/Action Points

3.1 It was noted that a meeting had not yet been arranged with the Chair of the Office of National Statistics (ONS) Advisory Group for Medical Research (AGMR) to discuss issues relating to dissent and non-response rates for a study considered by the AGMR. It was agreed to invite representatives of the AGMR to the next PIAG meeting to discuss this and other issues related to the work of the ONS carried out with Section 60 approval.

Action – Secretariat to invite the Chair of the AGMR and key staff at ONS to attend the next PIAG meeting.

3.2 Ms Meredith was concerned about whether the Advisory Group should be seeking to engage more with the UK Caldicott Guardians Council, and she felt that it was unfortunate that none of the lay members had been able to take on any additional commitment at this time. She proposed that perhaps they could consider undertaking attendance two or three times a year on a rotating basis. The Chair reported that she had not yet been invited to attend a Council meeting but agreed that links would need to be strengthened. She reported that the implementation of the Information Governance Review was likely to strengthen the position of Caldicott Guardians and may involve a larger role for PIAG in their development and support and therefore that the current situation was transitional.

Action – Secretariat to liaise with UK Caldicott Guardian Council Secretariat to discuss a way forward in the interim.

4. Secretariat Report

4.1 The Secretariat report was received and its contents noted.

4.2 National Joint Registry

It was noted that a letter about the consent rates had been sent to Sir Ian Carruthers, with copies to the President of the Royal College of Surgeons (RCS) in England and the Healthcare Commission, asking them collectively to consider how to improve consent rates for the National Joint Registry.

4.3 British Regional Heart Study (men) Annual Review report [1-07(d)/2004]

It was noted that this study was undertaken originally with consent but because of the elapse of time, it is unlikely that the consent obtained could still be considered as valid. The research team have re-sought and obtained consent from the vast majority of patients (83% response rate with 40 patients dissenting from access to their GP record). The research team were given Section 60 support to obtain data relating to the 17% of the surviving cohort who had not responded. A second attempt has now been made to obtain consent from those who had not previously responded with consent being given by 19%. The researchers asked for S60 support for the remaining 614 who had still not responded and provided a breakdown of reasons for non-response.

The Advisory Group acknowledged the importance of this study and accepted that Section 60 support was still required and would continue to be required: where the correspondence seeking consent was returned either because the address was incorrect, or because the patient was too ill to provide consent; and for those whose Registration had been cancelled or who were living overseas. Additionally for the 156 patients who had not responded to the request for consent but who had attended the study examination between 1998 and 2000 and about whom it may be reasonable to assume they would give consent but who may not have understood the need to return the consent form.

This review raised the issue of at what point non-response should be treated as passive dissent as, where consent was previously given, silence could be perceived as consent. It was agreed that:

i. It was difficult to establish firm rules about proportionality, and this would be different from one study to the next. It was agreed that this issue should be discussed further at the next meeting.

ii. The Secretariat should ask to view the information sent to patients to ensure it was appropriate.

iii. The study should be permitted to make one more attempt to contact patients who had either not responded or who had dissented to participating in follow up but who had not dissented to receiving the questionnaire, to ensure they are content for their contact details to be retained by the research team and to receive the questionnaire.

iv. The letter should make clear that non-response will be interpreted as dissent and therefore their details will be removed and they will not be contacted again. Additionally if they have access to telephone numbers it would be appropriate to make contact this way as they already had a relationship with patients and this may provide a better response than by post.

The Advisory Group also agreed that efforts should be made to provide information to participating patients about the interim findings of the study so that patients know that their contribution is making a difference to patient care.

Action: Secretariat to inform the Applicant of the Advisory Group's decision and seek the additional information

4.4 Adolescent Forensic Psychiatry Services Case Register 2-10(h)/2005

The Secretariat had received a request from this Registry to extend the range of data items collected. The Advisory Group agreed that a revised application should be submitted as the data being requested was sensitive and remained to be convinced by the supporting paper about the need to collect sexual preference data. Members also asked that the applicant test the feasibility and appropriateness of seeking consent with a group of patients being treated by these services.

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

4.5 Office of National Statistics

It was noted that the Office of National Statistics (ONS) had undertaken a consultation on the suppression of small cell numbers. It was noted that the consultation document was a considered appraisal of the issues but was proposing a significant change to the current situation. At present, the general 'rule' has been that any cell sizes less than five would be suppressed for publication. The consultation document was proposing to reduce this to cell numbers of one or two and on occasion zero where it increased the identifiability of other cells.

At a recent meeting between the Secretariat and the ONS AGMR Secretariat the issue of off-shore processing had arisen in relation to studies approved under the ONS approval [4-07(h)/2002]. As the studies had been reviewed they had found that six involved disclosure to researchers in Scotland, one in Italy and one in Canada. It was noted that these were historical studies. The Advisory Group agreed that provided that the only information being disclosed was mortality data that would otherwise be in the public domain, there was no problem with such disclosure including off-shore. Members felt that cancer registration data or other data not in the public domain must not be disclosed outside of England and Wales. It was felt that the option of having an English body with oversight for use of the data off-shore, in general, would not be appropriate. It was agreed that this should also be the subject of further discussion with the ONS at the next PIAG meeting.

Action – Secretariat to inform the ONS AGMR Secretariat

4.6 Deceased patient records

In its previous decision-making the Advisory Group has not, on the whole, concerned itself with deceased patients' data. Until recently there has been nothing in law which would indicate that deceased patients records are to be considered confidential. It has long been Department of Health policy and General Medical Council (GMC) guidance that medical records and the data they contain should continue to be treated as though they were confidential after death. Section 41 of the Freedom of Information Act, however, provides exemptions from disclosure, which include where a patient has an expectation of confidentiality, such as for medical records. This is currently under consideration by the Information Commissioner (ICO), as it is believed that improper disclosure could be actionable by the family of the deceased or recipients of the estate.

The Advisory Group therefore considered the boundaries of confidentiality with respect to patient information pertaining to the deceased with a view to establishing where the boundaries might lie to clarify for potential applicants what type of data would and would not require Section 60 support. These principles will be subject to review in light of further guidance from the ICO and as the Mental Capacity Act Code of Practice is developed further. There will be exceptions to this where there is statutory provision for, or prohibition of, disclosure.

The Advisory Group agreed the following principles in relation to how it would handle Section 60 enquiries and applications:

i. Clinical data for both the living and deceased were to be regarded as confidential. The threshold for justification of disclosure in relation to the deceased in most instances would be lower than for the living.

ii. For deceased adults the assent of families to the disclosure should be sought where practicable.

iii. Fraser-competent children would be treated the same as adults with respect to the use of their information. For non-competent children, parental consent should be the starting point for use of information for both living and deceased children. Section 60 may be used exceptionally. Causing further distress to parents during their time of grief may be a reason for not seeking consent from some parents but applicants would need to demonstrate that it was not practicable to seek consent at a later date and that the lack of near complete data would impair data quality significantly.

iv. Demographic data for the living is given to the NHS with an expectation of confidentiality and therefore should be treated as such.

v. Demographic data for the deceased is often publicly available e.g. death certification and therefore should not be regarded as confidential.

vi. Children are no different to adults with respect to how their demographic data should be treated.

vii. Cause of death currently is publicly available via death certification. There are good reasons why cause of death should not generally be available, however, if in future restrictions were to be introduced, this should not mean that such information would not be available for medical research and other medical purposes with the appropriate approvals.

5. Chair's Report

5.1 Meeting with Lord Warner

The Chair reported that she had met with Lord Warner in April to update him on the work of the Advisory Group and to discuss the Information Governance Review. It was noted that it had been a very positive meeting focussing on the possible legislative requirements for the proposed National Information Governance Board. The implementation of the Information Governance Review was still under consideration, however, the Advisory Group has been asked to provide a response to the issue of whether Executive powers should be pursued for the proposed Board or whether it should be Advisory. Members discussed this but felt unable to reach any firm conclusion without sight of the proposed Terms of Reference for the new Board.

5.2 Meeting with Baroness Finlay

The Chair reported that she had met with Baroness Finlay to discuss UK Biobank and a possible Cancer Registration Bill. It was a fruitful discussion even though it was apparent that there were clear differences in view between Baroness Finlay and the Advisory Group.

5.3 Meeting with the Royal College of General Practitioners

The Chair reported she had met with the President of the Royal College of General Practitioners (RCGP), Dr Mayur Lakhani, about the work of the Advisory Group and he had agreed to invite the Chair to give a presentation to the membership.

5.4 UKCRC Activities

The Chair drew members' attention to the outline of activities being undertaken by the UKCRC with respect to the use of patient information in research, attached to the Secretariat report. She reported on the involvement of Advisory Group members and the Secretariat in some of these activities, including her own on the steering group for a piece of Medical Research Council (MRC) commissioned research into public views on use of confidential information in medical research.

5.5 Academy of Medical Sciences (AMS) and University of Cambridge symposium on legal issues relating to the use of confidential patient information in research

It was noted that the Chair, Professor Catchpole and Ms Thomson had received invitations to attend a symposium on the legal issues pertaining to the use of confidential patient information in research to be held on the 24th June 2006.

6. Resubmissions from the previous meeting

6.1 Dr Foster Unit at Imperial College, University of London – Disclosure of NHS number to commissioning bodies [PIAG 1-05(c)/2006]

This application was considered alongside the application from Dr Foster Intelligence [2-05(c)/2006]. The Chair welcomed Professor Brian Jarman and Dr Paul Aylin from the Dr Foster Unit at Imperial College and Dr Lise Llewellyn and Dr Roger Taylor from Dr Foster Intelligence.

This application [1-05(c)/2006] had been considered at the meeting in March. It was felt that in light of the partnership between Dr Foster Intelligence and the Health and Social Care Information Centre that it would be helpful to meet with representatives from the Unit in order to seek clarification about their relationship with Dr Foster Intelligence. This and other issues had been raised with the applicant and they had submitted a written response in advance of the meeting. Subsequently Dr Foster Intelligence had also submitted an application for consideration and it was felt appropriate therefore that representatives from both organisations should be invited to attend in order to provide the above clarity about the relationship and lines of accountability.

With respect to the Imperial application [1-05(c)/2006], the Advisory Group were satisfied that there were effective measures in place to ensure that only legitimate users would be able to access the data and that organisations would only be able to gain access to data relating to patients they had treated. The Advisory Group were persuaded that there was additional benefit to the service provided by the Unit, for at least a significant proportion of Trusts. It was agreed that there had been reasonable efforts made to engage with patients and patient organisations. Ms Levenson proposed that they might consider undertaking a specific piece of work in relation to engaging with patients belonging to the high impact user cohort. The representatives from Dr Foster agreed that this would be a useful activity and they would consider it further.

It was noted that the Unit at Imperial was independent of Dr Foster Intelligence but that it was funded with a grant from Dr Foster Ltd. Only anonymised data was disclosed to Dr Foster Intelligence.

This application would extend the previous application for analysis of the data beyond the three years originally requested. Additionally it would provide a means of reporting the data analysed to Trusts in a way that they could then identify patients belonging to a particular cohort e.g. high impact users or patients with asthma, by age group etc. It was agreed that there was no barrier to the release of data back to the originating Trusts and that this aspect did not require Section 60. The extension of the disclosure of data to the Unit and the disclosure of sensitive data across organisational boundaries within the NHS was, however, of concern. With respect to the latter the Advisory Group were concerned about the needs of patients who may not want their GP to be made aware of their admission to hospital. Similarly the Venereal Disease Regulations prohibit disclosure of both the examination and treatment of sexually transmitted infections. There needs to be a means therefore of such information being filtered out prior to disclosure to Dr Foster.

The Advisory Group approved the application for 12 months while negotiations with the Secondary Uses Service (SUS) were undertaken. In time, much of this functionality would become available through SUS and then only pseudonymised data would be released to the Unit for analysis. This is subject to undertaking user involvement with high impact users and developing further the filtering mechanism to address the above issues.

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

7. Applications for Section 60 support

7.1 Department of Health (NHS Connecting for Health) - Disclosure and use of NHS commissioning and activity data [2-05(b)/2006]

The Advisory Group considered an application from NHS Connecting for Health for the collection and use of the commissioning data sets (CDS) via the Secondary Uses Service(SUS) for health service commissioning, planning and performance management purposes. Section 60 was required for at least a transitional period while the new system was established, both because of the limited functionality of the SUS sytem in its early stages and because Trusts were not yet in a position to be able to utilise pseudonymised data effectively. Additionally, there was a need to demonstrate that the new system would be able to deliver adequate data quality in order for users to have confidence in the data they would in future receive only in pseudonymised form.

The Chair welcomed Mr Jeremy Thorp and Mr Wally Gowing who had been invited to attend the meeting in order to answer members' questions relating to the application. A key issue was whether or not the purposes for the use of the data were sufficiently defined for the application to be approved under class regulations or whether specific support was required. Legal advice from the Department of Health's solicitors had been sought. It was noted that provided the purposes were restricted to health services purposes with robust conditions of approval to define these more precisely than the application had specified that it would be possible to approve this application under the class regulations. This caveat highlighted a key difficulty with the application, as the uses of the information are multiple and sometimes difficult to define.

The Advisory Group was concerned that there had already been significant slippage in terms of the timescale for delivery of the secondary uses service and that there was a risk of sliding into a longer term period of approval. It was agreed that if possible some milestones should be agreed in terms of developing a clear exit strategy from requiring Section 60 support.

It was noted that the SUS system itself would require access to identifiers on an ongoing basis in order to run analyses but that such identifiers would not necessarily need to be viewable by users. In the short to medium term there may need to be significant access to view identifiable data but that in the medium to longer term this would be reduced to a limited number of legitimate activities such as to meet statutory requirements, with patient consent or with Section 60 support. It was noted that SUS

would in time provide an exit from Section 60 for many of the other activities that had already received or were likely to require approval under it.

In addition to the breadth of the application, the Advisory Group was concerned by the scale of the Secondary Uses Service. It was apparent that this would become much bigger even than the NHS Wide Clearing Service (NWCS). Members were also unconvinced by the response to the user involvement question on the application form as this would appear to relate to National Care Record Service activities in general without specifically addressing issues related to the Secondary Uses Service. Additionally the Advisory Group would like to know what changes had been implemented as a result of patient and public engagement.

In light of the above, the Advisory Group agreed to provide Section 60 support under the class regulations for twelve months while either stronger grounds for the use of class support regulations was provided otherwise new regulations providing specific support or primary legislation would need to be prepared and laid before Parliament. If the secondary uses service or the NHS activities, it was supporting were going to require permanent and viewable access to identifiable data without other statutory support then it may be that primary legislation would be more appropriate. If it is uncertain what the long term requirements were likely to be, then specific support would be more appropriate.

Approval under the class regulations, was given for 12 months, subject to the following conditions:

i. That data can only be used for health service purposes (other than direct care, for which information is used with implied consent).
ii. Other uses will either require a statutory basis or a separate application for Section 60 support.
iii. If a short extension is required beyond the end of June 2007, then a revised application would need to be submitted.
iv. Access to SUS should be limited to the minimum number of staff feasible whilst also being operationally fit for purpose. Trusts need to ensure users have appropriate passwords for use with smartcards and users must be given training about not sharing smartcards or access.
v. With respect to Shared services organisations, they must have proper Information Governance policies in place before receiving data from SUS. Such policies must specify the lines of accountability.
vi. Development and confirmation of the approval status of the security and policy documents are required within 6 months.
vii. All those with access must provide assurance they have the required class of Data Protection Registration (Health records administration and medical research where appropriate) and will comply with data protection requirements and the Statement of Compliance.
viii. Non –NHS providers must have a contractual relationship with NHS CFH sign up to the Statement of Compliance and demonstrate that they have

appropriate security and confidentiality policies and procedures in place, such as that required under section 5 of the Advisory Group's application process.

ix. The Venereal Disease Regulations must be complied with, SUS therefore needs to ensure there is a filtering mechanism to ensure such data is only disclosed to SUS in anonymised form.

x. As indicated in the application, Strategic Health Authorities should only have access to aggregate data except for postcode data where they are undertaking geographical analysis.

xi. Section 60 support is only provided for established Commissioning Datasets. New activities and purposes such as PBR data flows will require a separate Section 60 application, other statutory basis or should use effectively pseudonymised data.

xii. The Advisory Group has identified that there is a need for further training for NHS management and Informatics staff – it is essential therefore that the training tool applicable for all NCRS is developed without interruption to funding, alongside the Information Governance toolkit.

xiii. If anonymised/ pseudonymised data is fit for purpose then that is what should be used.

xiv. The conditions of approval need to be communicated to PCTs, Shared Services organisations, SHAs and the fact that this is envisaged to be an interim measure until alternative legislative support is in place and SUS is fully functional and able to provide pseudonymised data. Section 60 support must not be perceived as endorsing the status quo.

xv. With respect to clinical audit, the Advisory Group has previously agreed that local clinical audit following the care pathway and quality assuring the care given, may use identifiable data but that national/ regional comparative audit should be using pseudonymised data or have its own Section 60 support.

xvi. Cohorts of patients such as those at risk of admission to hospital should be identified by clinicians, and the usual referral process followed for care.

xvii. Inclusion of patients on a disease register, in general, this should be undertaken only with consent.

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

7.2 Dr Foster Intelligence -To provide a management information function for the NHS [2-05(c)/2006]

Dr Lise Llewellyn and Dr Roger Taylor described the relationship between the Unit at Imperial and Dr Foster Intelligence. They presented their application as not duplicating the work of the Unit but to request additional access to the data held at the Unit in order for the more routine data analyses to be undertaken by Dr Foster Intelligence staff, freeing up the academic unit to focus on developing tools. Clearly in due course there will be a relationship with the Secondary Uses Service and information will be able to be accessed and analysed via this route but that it would take some time yet for this to be functional.

Members of the Advisory Group responded that the above intention was not clear from the application. It was agreed that this application was a useful starting place for discussion but that it could not be approved in its current form as it was not specific enough about the purposes for using the data, nor about precisely who would be accessing the data, nor what benefit there would be to patients or the public. Members agreed to invite Dr Foster Intelligence to submit a revised application clarifying the above questions.

Additionally, it was agreed following discussion that if Dr Foster Intelligence would be acting as the agent of the Health and Social Care Information Centre (HSCIC) then the Information Centre should be co-signatories to the application.

Action – Applicant to be informed of the Advisory Group's decision

7.3 National Cancer Services Analysis Team (NatCanSAT): Analysis of 18 Weeks target from referral to treatment [2-05(d)/2006]

This application was to undertake analysis of attendances at hospitals in England in order to assess progress towards the target for 18 weeks from referral to treatment. This was extending a pilot recently developed using pseudonymised data held in the NatCanSAT data warehouse for Cheshire and Merseyside SHA. A number of questions had been raised with the applicant nearly a month in advance of the meeting but they had only submitted a response the day prior to the meeting.

The Advisory Group noted that this applicant had again submitted this application on an out of date form and had failed to provide sufficient detail. Although the email response had addressed many of the concerns and questions raised by the Secretariat, the Advisory Group agreed to reject the application in its current form but that the applicant could re-submit using the current version of the application form and include the supplementary information provided subsequently.

In addition, the Advisory Group made the following observations, which should be addressed in any re-submission:

i. The Advisory Group was concerned about the applicant's perception of consent as being impracticable as it would require clinician time. By itself this is not a sufficient reason. More detail is required such as the impact of the size of the cohort, the relative difficulty of contacting patients retrospectively, explaining the nature and risk of data bias.

ii. The applicant has submitted many applications but still does not have adequate user involvement mechanisms in place. In addition to reporting on what user involvement mechanisms are in place, the application should include what changes or additional safeguards have been introduced as a result of this involvement. The Group agreed that it would not support further applications from NatCan Sat in the future unless it was convinced that riobust and meaningful user involvement mechanisms were built into studies.

iii. With respect to this particular project, members felt that the applicant had not made a strong enough case for why identifiers would be required.

iv. Similarly the 18 week wait target is well monitored at a local level, it is unclear what additional value this activity would provide to reporting of local analysis.

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

7.4 University of Oxford Kadoorie Centre for critical care research and education: Intensive Care Outcome Network Study (ICON) [2-05(e)/2006]

The purpose of the application is to establish a registry of patients discharged from intensive care units after a stay of at least 24 hours. The Registry will be used to study the long term psychological morbidity and changes in health related quality of life over time following discharge from ICUs and long term survival.

Section 60 support was sought to identify the cohort of patients in order to seek their consent, and for flagging on the NHS Central Register (NHSCR), to check patients' vital status, so that families of deceased patients are not distressed by being approached unnecessarily.

The Advisory Group agreed this was an important area of study, however members felt that an alternative approach may be appropriate. The Advisory Group proposed that the initial approach with the information packs should be made by the ITU co-ordinator at the Unit where the patient was treated. This would obviate the need for any disclosure to the researchers prior to consent. The Advisory Group accepted that it was reasonable for the ITU co-ordinators to check vital status prior to writing to patients in order not to cause distress to bereaved families if the patient had died in the interim.

If this approach is practicable then Section 60 support would not be required provided no linkage e.g. with Intensive Care National Audit and Research Centre (ICNARC) is undertaken prior to obtaining consent. If there were unforeseen difficulties with the proposed approach then the applicant may come back to the Group with additional clarification for why this approach was not practicable to re-consider this application.

Additionally, as this study was proposing to collect data relating to patients in Scotland, it was noted that the applicant should also inform the Community Health Index (CHI) Advisory Group of its proposals.

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

7.5 Lancashire Teaching Hospital Trust: Survival rates from out of hospital cardiac arrest in Lancashire [2-05(f)/2006]

This application was for a student research project to ascertain survival rates for patients having a cardiac arrest out of hospital and identify whether bystander cardiopulmonary resuscitation improved survival rates. Identifiable data was required for a short period to link data from the ambulance trust with hospital outcome data. Analysis would only be undertaken on anonymised data.

Although the Advisory Group does not consider the quality of the science within its decision-making, as this is the responsibility of Trust Research review panels, members had some concerns about whether the data collected from the ambulance trust would be fit for purpose in terms of meeting the objectives of the study. The Secretariat was asked to ascertain if the study had been considered by a review panel. Members also agreed to discuss how to handle where there were questions about the quality of the science at the next meeting.

The application had also not addressed user involvement adequately. As the applicant only required access to identifiable data for a short period of time, however, the Advisory Group approved the application subject to research panel review and user involvement being undertaken.

Action – Secretariat to inform the applicant of the Advisory Group's decision and to include on the next agenda, handling of applications where there were questions about the scientific validity of the approach.

[Note from the Secretariat – The applicant has advised that user involvement has been initiated via Heartstart but the results, both in terms of whether the use of patient data was regarded as acceptable and feedback on the research design, were unknown at the time of application].

7.6 Merseyside and Cheshire Cancer Registry: Study into what factors influence socioeconomic inequalities in colorectal cancer survival? [2-05(g)/2006]

This application was for a research study involving data held by multiple registries and linking to HES data. It was noted that this was for a large cohort of patients (over 40,000 cases) with a majority of deceased cases, and with a risk of significant data bias, if consent were sought. Minimal identifiers would be provided by the registries for analysis purposes. The Advisory Group approved the application subject to user involvement and that the security arrangements at the Registry being improved in line with the recommendations of the Security risk review undertaken.

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

7.7 UK Centre for Evidence in Ethnicity, Health & Diversity (CEEHD): Ethnicity: Colorectal Breast & Cervical cancer screening uptake and outcome patterns corrected for socioeconomic status [2-05(h)/2006]

This aim of this study is to examine uptake of colorectal, breast and cervical screening for the minority ethnic populations in Coventry and Warwickshire and compare uptakes for different ethnic sub-groups (corrected for socioeconomic and demographic characteristics) with uptake for the majority (white) population.

The study required the names of patients in order to conduct name analysis to identify or validate ethnicity. NHS number was required for linkage and postcode for deprivation scoring. Once analysis of the names had been completed and deprivation scoring allocated, names would be removed and postcodes reduced.

Members were concerned about the efficacy of a programme to allocate ethnicity on the basis of names. There was recognition, however, that in light of generally poor data quality with respect to the recording of ethnicity, it was probably the best that could be achieved currently. It was noted that user involvement at the centre was inadequate.

The Advisory Group agreed to approve the application as the data only needed to be in identified form for a very short period, subject to:

i. Establishing proper patient and public engagement with community groups representative of different ethnic populations.
ii. Assurance from the Director of the Centre that other activities undertaken by CEEHD using patient identifiable data would seek 60 support.

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

7.8 University of Oxford: **I**nclusion for **D**SPD: **E**valuating **A**ssessment and treatment (IDEA) [2-05(i)/2006]

This application was for a study into Dangerous and Severe Personality Disordered (DSPD) patients, their assessment and treatment. There is little evidence about what forms of care and treatments are effective for this group of patients. The applicant required prison identifier numbers, Hospital number, date of birth and date of admission for longitudinal linkage. The applicant was wanting to collect sensitive data including psychiatric classification, and whether they had committed violent or sexual offences. A key argument made by the applicant was that this group of patients would be likely to dissent if consent for participation was sought. Such dissent was described as a feature of the disorders experienced by these patients (i.e. that patients would be prone towards being deliberately obstructive as part of their condition) but not generally from a lack of capacity to make such decisions.
The Advisory Group was concerned that the feasibility of seeking consent had not been tested with a group of patients. It was also noted that there were two categories of patients about which data was sought: those admitted to the specialist units and those who had been referred but who were not accepted onto the units and who were incarcerated elsewhere. The application did not provide justification for why identifiable data was required and why the data could not be anonymised at source before being submitted. Additionally, members felt strongly that Section 60 should not be used to override patient dissent and that this presented a significant difficulty in considering this application. In light of the above it was agreed therefore to refer this application until these issues had been addressed.

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

The Advisory Group also agreed that it would be useful to bring together a small group of relevant stakeholders to discuss these and related issues in relation to research and working with people in secure accommodation, which would tie in with work on developing a code of practice for this area.

Action – Secretariat to convene this meeting in consultation with the Chair

7.9 Northgate Information Systems: National Joint Registry [2-05(j)/2006]

This application was a new application for the National Joint Registry, which was approved in December 2005 for AEA Technology, but the Registry had since moved to Northgate Information Systems and hence the need for a new application. It was noted that the Registry was commissioned by the Department of Health. The new application had included data about improved consent rates over the time the Registry had been in operation. It was noted that there had been a significant increase in the last twelve months in those achieving more than 90% consent rates, however there was a remnant cohort which appear to be problematic. It was unclear whether this was because consent was not being sought; or that hospital processes had not been established to ensure that consent status was known by the data entry clerk at the point of entry; or a staff capacity issue. Section 60 support was sought to allow access to identifiable data to search for the NHS number and improve linkage within the registry and also for analysis purposes with a view to identifying problematic products or procedures, or cohorts of patients with specific needs that require another approach.

Because of the quality of the application and the fact that considerable work had already been done to improve consent rates, the Advisory Group agreed to approve the application for two years subject to the following conditions:

i. That it was understood that consent was still required but that where consent had not been sought or it was unknown whether consent had been sought then Section 60 could be utilised to obtain identifiable patient data. Particular care would need to be taken to ensure that dissent was respected and no identifiers submitted in this circumstance.

ii. Where Section 60 has been utilised, once the NHS number has been traced or validated through NSTS, name and address should be removed and postcode and date of birth reduced.

iii. That the Registry continues to demonstrate year on year improvement in consent rates in its annual review.

iv. That consideration be given to maintaining valid consent and appropriate data destruction (de-identification) over the longer term.

v. That the Secretariat be informed of new linkage arrangements with HES or PEDW.

vi. The possibility of including consent to participation in the Registry on the consent to treatment forms should be considered. It would need to be made clear to patients that these are separate consent processes and that refusal to be part of the registry would not affect their care and treatment.

vii. With respect to independent treatment centres (ITCs), where it is not already the case, that there was a need for commissioners to make it a contractual obligation on ITCs to participate in the Registry and for them to offer participation in the Registry to patients.

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

8. Annual Review of the Regulations

The Advisory Group gave brief consideration to the Annual Review of the Regulations report [PIAG2-06/2006]. It was agreed provisionally to approve the report subject to further consideration of the details via email discussion. Final approval of the annual review report and of the particulars of the Cancer Registries (UKACR), the Health Protection Agency (HPA) and National Clinical Audit Support Programme (NCASP) to be undertaken by Chair's action following the email discussion.

Action – Secretariat to facilitate the above process

9. Independent sector issues

The Advisory Group agreed to provide comment on the briefing document [PIAG 2-07/2006] by email to the Secretariat.

Action: All members to comment

10. Fast track application process

The Advisory Group agreed to consider and comment on the proposed fast track application process [PIAG 2-08/2006] and submit responses by email to the Secretariat. It was agreed that final approval should be by Chair's action.

Action – All members to consider and comment

11. Future meetings for 2006

Monday 11th September 2006
Wednesday 13th December 2006