PATIENT INFORMATION ADVISORY GROUP

Meeting on Tuesday 15 March 2005

Minutes

1. Present

Members: Professor Joan Higgins (Chair), Professor Michael Catchpole, Dr Tricia Cresswell, Dr Fiona Douglas, Ms Stephanie Ellis, Mr Michael Hake, Ms Ros Levenson, Ms Barbara Meredith, Professor Sir Denis Pereira Gray, Dr Peter Rutherford and Dr Michael Wilks.

In attendance: Mr Patrick Coyle, Mr Alistair Donaldson, Mr Sean Kirwan, Ms Karen Thomson and Ms Anne Ward

2. Welcome and apologies

2.1 The Chair welcomed the new members to the meeting and introduced Mr Patrick Coyle, a consultant surgeon from Wales and the Chair of the Security and Confidentiality Advisory Group for the Nationwide Clearing Service, Hospital Episode Statistics (HES) and the National Strategic Tracing Service (NSTS), Mr Alistair Donaldson who leads on information security management with the Department (& NPfIT). He provides advice on the security aspects of the applications for Section 60 support to the Advisory Group. It was noted that Mr Sean Kirwan was attending in place of Mr Jim Shannon, the Confidentiality policy lead and the Advisory Group's link with the Department of Health.

2.2 Apologies were received from Dr Peter Furness, Dr Roy McClelland, Ms Julia Palca, Professor Martin Severs and Mr Jim Shannon.

3. Minutes of the last meeting

The minutes of the previous meeting of the Advisory Group that had taken place on Tuesday 7 December 2004 [PIAG 4-03/2004] were agreed to be a true record subject to some minor amendments.

4. Matters arising

The Advisory Group considered the Secretariat report and the following items were discussed:

4.1 NatCanSat Annual Review report

Members of the Advisory Group were concerned that there was such poor matching to HES data without full date or birth and asked the Secretariat to ascertain why this was the case.

Action: Secretariat to investigate why full date of birth was a requirement for matching.

4.2 BPSU prospective process for Section 60 support

British Paediatric Surveillance Unit of RCPCH, HPA, ICH(L) – Epidemiological surveillance of rare childhood disorders and infectious diseases, multiple studies [PIAG 4-08(b)2004]

The report from the Secretariat on the progress that had been made with respect to developing a prospective process for applications under the auspices of the BPSU, was noted. The BPSU would re-submit an application to cover the studies they currently support and work with the Secretariat to streamline the application process for new studies by developing a joint application form for consideration by the respective bodies.

Additionally, Members were concerned that the BPSU had reported an inconsistent approach to the use of the NHS number by MRECs. The Secretariat was asked to prepare a draft position paper on this for the next meeting. In addition, it was agreed to raise this with COREC.

Action: Secretariat to work with the BPSU to progress the streamlining of processes. Secretariat to prepare draft position statement on the use of the NHS number for the next meeting.

4.3 Lord Warners' Ad Hoc Advisory Group in NHS Research Ethics Committees.

The Chair reported that Lord Warners' Ad hoc advisory group in NHS Research Ethics Committees was just coming to the end of its deliberations. She reported that her meeting with the group had been positive. Following this, the Chair had met with Lord Hunt, Chair of the National Patient Safety Agency (NPSA). As part of the re-structuring from the Arms Length Bodies Review, the NPSA would be taking over responsibility for COREC from 1 April this year and this was the focus of their discussions. The outcome of the meeting was that Lord Hunt and the Chair agreed to write a joint letter to Lord Warner indicating that the NPSA and the Advisory Group would work together to streamline REC and PIAG application processes in order to reduce the administrative burden for researchers.

4.4 Academy of Medical Sciences (AMS) research into use of patient information in research

The Chair reported that following the Advisory Group's submission to the AMS, the Chair had arranged to meet with Professor Robert Souhami, Chair of the Committee responsible for this research project and Dr Helen Munn manager for the study.

4.5 Annual report

It was noted that as the Annual Report had taken some time to finalise that a designed and printed version would only be produced for July 2004 – June 2005, but that this Annual Report would be made available on the website. Members suggested that the 2005 report should include examples of good practice. It was also proposed that a short leaflet about the work of the Advisory Group should be prepared and disseminated in order to raise the profile of the group among target audiences.

Action: Secretariat to draft a leaflet about PIAG and draft 2005 report to include examples of good practice.

4.6 Draft Development Strategy

The draft development strategy was accepted as the focus for the next phase of the Advisory Group's work. A number of further suggestions were made about how the identified goals might be achieved.

It was agreed that for the next meeting a paper outlining the issues that need to be addressed and who the Advisory Group might work with in order to ensure they are addressed. In some instances, organisations may well already be engaged in taking these issues forward.

Action: Secretariat to draft a paper

During discussion, the need to ensure that the public information campaign for the National Programme for Information Technology was well balanced was identified as a key priority and timely. It was agreed that the Chair should write to the Secretary of State to advise what the group felt was appropriate to include in such public information.

Action: Chair to write to the Secretary of State

The Chair reported that the Care Record Development Board would be endeavouring to co-ordinate activities and to map who was working on which areas. The Advisory Group noted that three outputs from the Ethics Advisory Group had been accepted by the CRDB and Programme Board: Ethical Principles, opt in and opt out report and the Care Record Guarantee which had been sent to ministers but which was currently being considered by legal advisers.

5. University of Bristol Application:

Evaluation of population based screening for localised prostate cancer in the UK, case note review [PIAG 3-06(e)2004].

5.1 The Advisory Group considered the additional information supplied by the University of Bristol in support of this application. Professor Catchpole and Dr Cresswell presented the application for the benefit of new members. A discussion then took place with Professor Jenny Donovan and Dr Richard Martin from the research team at the University of Bristol.

After their withdrawal from the meeting, the Advisory Group considered the application.

5.2 It was explained that this research group had already received Section 60 support to enable linkage with ONS data so that when one of the control group was identified as having prostate cancer or was recorded as having died of or with prostate cancer that the research team would be notified. The new application was seeking Section 60 support to access the records of the estimated 6000 men who had received a diagnosis or cause of death as prostate cancer. The Advisory Group had accepted that there was a serious risk of contamination if consent was sought from the control group prior to onset of prostate cancer and this had been the reason for supporting ONS linkage. This argument did not apply however once the diagnosis had been made. The research team put forward the argument that seeking consent from 6000 men once diagnosed with prostate cancer was likely to be problematic as there was an expectation that the non-response rate could possibly be as high as 50% with around 4% actively dissenting. This would mean the control arm would be under-powered based on the 230,000 cohort, and the results consequently less valid.

5.3 The importance of this study as a means of settling the still outstanding and key questions about the benefit of screening for prostate cancer, and whether it impacted on life expectancy, or whether it might reduce the need for radical and disabling surgery, were emphasised. Other big international studies had failed to address these questions successfully.

5.4 This application, however, was also perceived by members of the Advisory Group as a test case in terms of how information may be used in research. Part of the difficulty was that this research project was already underway. If it had been a new study it would be highly unlikely to obtain Section 60 support. It was also clear that in due course this was the type of research, which the Secondary Uses Service would be able to support through the provision of accurate, anonymised or pseudonymised data.

5.5 The advisory group was very concerned by the proposal that Section 60 should be used to overturn the decision by patients not to participate either through active dissent or by not responding to the request to participate. The advisory group was also concerned at the length of this study as it would enable the research team to retain identifiable data for many years. It also became clear that aside from considerations of confidentiality, there was a fair processing requirement under data protection to inform people about how their information is or might be used and to provide them with a mechanism to opt out if they objected. Applicants for Section 60 support are still required to conform to data protection requirements.

5.6 After considered and lengthy discussion the Advisory Group agreed that it could not approve the application and that consent should be sought from the 5-6000 men that this applied to, if for some reason this proved impossible or extremely difficult, the applicant could re-apply, following a

reasonable pilot, specifying the reasons consent had been so difficult to obtain and the Advisory Group would re-consider the application. It was noted that as patients were dispersed across a large area and that these diagnoses would be made over a ten year period it would not place a significant burden on any one clinician or GP practice to seek and obtain consent during the course of ongoing clinical care. The Advisory Group therefore did not feel that there was a robust justification for the use of such patient information without consent. The argument that some men may be very elderly and therefore may not be informed of their diagnosis was felt to be inappropriate in all but perhaps the most vulnerable cases or where there were other complicating factors such as capacity issues. Where resources had been put into obtaining consent, specifically in the Protect arm of the study, few had dissented from having their records looked at. It seemed then that this was an administrative issue rather than a real difficulty in seeking and obtaining consent.

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

5.7 During the course of discussions the following wider issues emerged which the Advisory Group felt needed to be raised not only with the research team for this project but with the research funding community and the Department of Health:

- The Advisory Group felt it was regrettable that many people in the Department, research funding bodies and a Research Ethics Committee had looked at this research project positively but had apparently failed to consider the issues of confidentiality and consent. As a consequence of this there was a risk that the CAP arm of the study may be under powered because of a failure to invest in informing patients in this arm of the study.
- It was not clear why funding bodies had not put resources into the cancer registries, who already have Section 60 support, to enable them to collect the relevant data to facilitate this research project.
- The Advisory Group felt dismayed that such significant sums of public funding had been put into a research project that had given such little consideration to issues of confidentiality and consent for the use of information.

5.8 It was noted that a letter had been received from Cancer Research UK in support of the application and highlighting a number of issues in relation to the Advisory Group's consideration of the application. It was agreed that the Chair would respond to this on behalf of the Group.

Action: Chair to respond to Cancer Research UK and to the Department of Health – letter to be circulated to members for comment.

6. Working with the Information Standards Board (ISB)

6.1 The Chair reported that she had had brief discussions previously with Dr Martin Severs about how the ISB and the Advisory Group might work more effectively together but that this discussion had been about working at a strategic level. The paper drafted by Ms Jane Millar was proposing that the two bodies work together at an operational level.

6.2 Members agreed that a strategic approach was the most appropriate way of working with the ISB. Members felt that they needed to know more about how the ISB functioned before being able to consider how the Advisory Group might have an appropriate level of input, whilst not being part of the whole development process. Following discussion it was agreed to seek observer status on the ISB. If this was acceptable to the ISB, it was agreed that Ms Stephanie Ellis would take on this role and report back to the Advisory Group. It was also agreed to invite Ms Millar to a future meeting of the Advisory Group to present the work of the ISB and discuss how we might work together more effectively.

Action: Secretariat to contact Ms Millar to seek observer status and to invite to a future meeting.

7. Patients who lack capacity

Members noted the briefing documents on the Mental Capacity Bill and the discussion document prepared by Mr Jim Shannon. Given time constraints, it was agreed to discuss this again at a future meeting and consideration given to drafting a response to the Draft Code of Practice.

8 Historical studies wanting to update original information

The Advisory Group noted the correspondence from Professor Swerdlow with respect to historical studies that require access to information for data cleansing and completion purposes. As this required access to new information, the Advisory Group agreed that an application for Section 60 support was required but that it was not necessary to complete the full application form. The Secretariat was asked to advise on which sections of the form would still be required.

Action: Secretariat to review application form for historical studies undertaking data cleansing and completion.

9. Applications from last meeting

Royal Free Hampstead NHS Trust – North-Central and East London Child Health record linkage [PIAG 4-08(e)/2004]

The applicant had asked for guidance from the Advisory Group about how it might adapt the projects included in its application to address the concerns raised by the group. The Applicant had provided some additional information for consideration. Having considered this, the Advisory Group felt that it was important to separate out the activities incorporated into this application. For the projects related to monitoring children at risk, it was clear that consent was not appropriate and that identifiers were

required for record linkage, these related projects therefore required Section 60 support and the applicant was advised to re-apply specifically for this activity. Related to this, with respect to the development of the child electronic health record, the advisory group felt strongly that this should be run as a pilot for the National Programme for Information Technology and would fit well into the 'Do once and share' work being developed by Dr Muir Gray. It was important that this work was not being undertaken in isolation either from the National Programme or from local child protection teams and these relationships should be made clearer in the application.

For work related to monitoring long-term health outcomes, in general, this should be undertaken with consent. The Advisory Group agreed that monitoring the incidence of neonatal bacteraemia was integral to the provision of good care and therefore consent could be implied from consent to treatment. This work therefore did not require Section 60 support. For the evaluation of babies admitted neonatal intensive care units, this was a research project and therefore a separate Section 60 application should be made if identifiers were required and it would be inappropriate to seek consent. The application would need to make clear both why identifiers were needed and why it was not appropriate to seek consent e.g. at the point of discharge.

Action: i) Secretariat to provide guidance to the applicant

10 Applications

10.1 Mental Health Act Commission: *Count me in: National Mental Health and Ethnicity Census 2005, England and Wales* [PIAG 1-08(b)/2005]

The Advisory Group considered an application for Section 60 support from the Mental Health Act Commission (MHAC) for a Census of Mental Health and Ethnicity among both detained and voluntary patients who would be inpatients on 31 March 2005. Mr Michael Hake declared an interest as a Healthcare Commissioner and therefore did not participate in the discussion. The Advisory Group noted that MHAC already had statutory access to the records of detained patients but that as their role for this project had been extended to include voluntary patients, Section 60 support was being sought for the collection of data from the records of voluntary patients. It was noted that only very limited identifiers would be required for the Census but that there would also be a data quality audit on a proportion of records. The Advisory Group felt that MHAC had taken sufficient steps to pseudonymise the data and that including the records of voluntary patients within the data quality audit was justified to ensure the quality of record-keeping applied equally to both detained and voluntary patients. There were a number of security concerns, specifically that the security policies needed to apply to specifically to MHAC and that there was a contractual obligation to maintain confidentiality on the part of the outsourced IT provision to support the census.

The Advisory Group approved the application subject to the security and contractual issues being adequately addressed.

Action: i) Secretariat to inform the applicant of the decision

ii) Details of the application to be published on the Register of activities carried our with Section 60 support, once the conditions had been met.

[Note from the Secretariat: These outstanding issues have been addressed and final approval given].

10.2 University of Liverpool, Division of Medical Imaging: *Retrospective secondary analysis of breast cancer risk factors from Liverpool Breast Cancer Risk Factor Study (1979-1986)* [PIAG 1-08(c)/2005]

The Advisory Group considered an application for Section 60 support from the Medical Imaging Division of the University of Liverpool to undertake a retrospective analysis of breast cancer risk factors using data collected as part of the Liverpool Breast Cancer Risk Factor study. The new analysis would involve digitalising mammograms taken at the time and linking with NHS Central Registry data to identify women who had subsequently developed breast cancer to try to identify risk factors from the mammograms or other information obtained at the time. The information was obtained with consent originally, however the consent could not be said to still be valid after such a long interval, even though this study was in keeping with the aims of the original study. It was noted that this information was already held by the University. The applicant had applied to re-access these records from their own archives in order to pseudonymise them following linkage with the ONS. The Advisory Group agreed to approve the study with the conditions that following linkage only effectively anonymised data would be retained and that identifiers would be destroyed. Additionally that appropriate security measures were in place.

Action: i) Secretariat to inform the applicant of the decision

ii) Details of the application to be published on the Register of activities carried our with Section 60 support, once the conditions had been met.

10.3 North Tyneside General Hospital: *A study to research the impact of the Northumbria Safety Camera Partnership on the incidence of casualties resulting from road traffic accidents and to assess the subsequent use of health services within the region over a six year period* [1-08(d)/2005].

The Advisory Group considered an application for Section 60 support from North Tyneside General Hospital to research the impact of safety cameras on the incidence of casualties resulting from road traffic accidents.

The Advisory Group did not consider that there was sufficient justification for accessing identifiable data without consent. There were also a number of security concerns. The advisory group rejected the application and advised that the applicant should obtain consent.

Action: Secretariat to inform the applicant of the decision

10.4 NHS Coronary Artery Disease Clinical Research Network, BHF Research Centre and Leeds University Clinical Trials Unit: *SPACE ROCKET Trial* [PIAG 1-08(e)/2005]

The Advisory Group considered an application for Section 60 support from the NHS Coronary Artery Disease Clinical Research Network, BHF Research Centre and Leeds University Clinical Trials Unit to conduct an open label comparative investigation of efficacy, tolerance and health in 2,072 patients randomised to Rosuvastatin or 'standard' Simvastatin therapy following hospital admission for new definition myocardial infarction (heart attack). The SPACE ROCKET Trial: Secondary Prevention of Acute Coronary Events. Reduction of Cholesterol to Key European Targets.

Following discussion the Advisory Group felt that how the relationship between the research team and patients was established was very important and therefore whilst they approved the application it was subject to a number of conditions, namely that:

- There was confirmation that the initial approach to patients will be made by clinical staff, prior to introducing the CRN.

- Appropriate information would be made available to clinical staff so that they could identify if it would be inappropriate to approach a particular patient.

- The cooling off period to allow patients to consider whether or not to participate should be at least 24 hours as some patients may require longer and the advisory group felt this should be accommodated.

- Consent should be sought from people who dissent from participation in the study to hold their identifiers until the end of the recruitment period in order to not approach them multiple times.

- Data security with respect to the use of laptops and processes related to the transfer of data, were clarified and if necessary strengthened.

The approval of the application was also subject to the outcome of the planned monitoring visit to Leeds General Infirmary on 21 March 2005.

Action: i) Secretariat to inform the applicant of the decision

ii) Details of the application to be published on the Register of activities carried our with Section 60 support, once the conditions had been met.

10.5 University of Leeds and Leeds Teaching Hospital Trust: *BEAUTIFUL study* [PIAG 1-08(f)/2005]

The Advisory Group considered an application for Section 60 support from the University of Leeds and Leeds Teaching Hospital Trust for a study into the effects of a new drug on cardiovascular events in patients with stable coronary artery disease and left ventricular systolic dysfunction (called the

BEAUTIFUL Study). It was noted that whilst in many ways this was similar to the SPACE ROCKET study it was different in that this was a much larger multi-centre study. Leeds Teaching Hospital Trust appears to be the lead NHS sponsor, however, there are a number of other NHS participating centres whose legal obligations may be affected by this application and whose legal / common law duties and commitments are unclear and untested. It was unclear whether the University of Leeds as the recipient for the data from all the participating centres have honorary contracts with all the participating Trusts or whether this application relates only to the participation of Leeds Hospital Trust. If it is intended that this application covers all the participating sites then evidence that all the participating centres have agreed to follow the same methods of data handling and to comply with the conditions set by the Advisory Group would need to be supplied. The issue of honorary contracts has been discussed in the past and the key question in relation to this is to whom these individuals are legally responsible. The answer to this is likely to determine which body should be responsible for definition and implementation of security policy and processing practices. As it stands the scope of the application and the supporting documentation supplied makes it unclear whose security policy governs which part of the proposed processing.

Additionally the Advisory Group felt that user involvement for this study was poor and should be strengthened in at least one participating centre. Members also felt the information sheets for patients could be clearer.

Following discussion the Advisory Group agreed to approve the application with the following conditions:

- That there was confirmation that the initial approach to patients will be made by clinical staff, prior to introducing the CRN.

- That appropriate information would be made available to clinical staff and that the agreement of the treating consultant would be sought to ensure that patients were not approached inappropriately.

- That a user involvement exercise was undertaken to obtain the views of patients on the design of the trial and the use of information to support it and that this would be used, where possible, to inform the conduct of the trial. It should be made clear to those involved that for this project there may be limitations on what could be altered at this point but that the exercise would be used to inform the conduct of this study and future research.

- That the cooling off period to allow patients to consider whether or not to participate should be at least 24 hours as some patients may require longer and the advisory group felt this should be accommodated.

- That consent should be sought from people who dissent from participation in the study to hold their identifiers until the end of the recruitment period in order to not approach them multiple times.

- That the outstanding data security issues were clarified and strengthened where necessary.

- That the relationship between the University of Leeds and the other participating centres was clarified and that they agreed to comply with the requirements of PIAG's approval.

The approval of the application was also subject to the outcome of the planned monitoring visit to Leeds General Infirmary on 21 March 2005.

Action: i) Secretariat to inform the applicant of the decision

ii) Details of the application to be published on the Register of activities carried our with Section 60 support, once the conditions had been met.

Additional comments, which have broader implications, included the concern that the consent form to participate included the statement that representatives of the company involved may access any medical records of participants. Members felt this was unnecessarily broad and should be limited to relevant records. The Advisory Group recognised that this was a broader issue and therefore one to address with COREC rather than with this research team.

10.6 National Cancer Services Analysis Team: *Analysis of children's attendances at Hospital* [PIAG 1-08(g)/2005].

It was unclear from the information given in the application form, what data was already held and what linkage was being asked for. It was also unclear why parents and patients themselves were not being asked what the issues were with respect to transport to hospital. This application was therefore referred and would be re-considered at the next meeting following additional information to address the above questions, being supplied.

Action: i) Secretariat to inform the applicant of the decision

12. Future Meeting Dates

The meeting dates for 2005 will be:

6 June

12 September

5 December