PATIENT INFORMATION ADVISORY GROUP

Meeting on Monday 13 September 2004

1. Present

Members: Professor Joan Higgins (Chair), Professor Michael Catchpole, Mr Patrick Coyle, Dr Tricia Cresswell, Mr Michael Hake, Ms Barbara Meredith, Professor Sir Denis Pereira Gray, Mrs Shahwar Sadeque, Dr Michael Wilks and Ms Karen Thomson.

In attendance: Mr Sean Kirwan and Miss Victoria Lowther

2. Apologies

2.1 Apologies were received from: Ms Helen Miller, Ms Julia Palca, Ms Helen Darracott.

3. Minutes of last meeting

3.1 The Minutes of the previous meeting of the Advisory Group that had taken place on 7 June 2004 [PIAG 3-02/2004] were agreed to be a true record.

4. Matters arising/action points

Clinical Audit

4.1 Mr Kirwan informed the Group that in response to the Advisory Group's decision at the last meeting on clinical audit the Department of Health placed a note in the Chief Executives bulletin. A link to the bulletin can be found on the 'What's new' section on the Advisory Group's website. Mr Kirwan explained that the Secretariat have now added further advice in response to queries the Secretariat were receiving from NHS staff.

BMJ Article

4.2 Mr Kirwan explained that the Secretariat had posted a 'rapid response' on the BMJ website to the article. 'Data Protection, informed consent

and research' by Professor Julian Peto, that had been published by the Journal in May. The BMJ had subsequently published the response in the journal dated 4 September, volume number 329. Professor Higgins also added that she had received favourable comment from Professor Aidan Halligan from the National Programme for IT on the response.

Previous Applications for Section 60 Support

4.5 At its previous meetings the Advisory Group requested that additional information be provided before the applications could be approved, as follows:

(i) Application from Manchester NHS Agency

At its previous meeting the Advisory Group had considered an application for Section 60 support from the Manchester NHS Agency for a register to track the clinical status and spread of CVD and diabetes in patients [PIAG 1-07(h)/2004]. The Advisory Group had expressed the following concerns about the application:

- That it would be wrong for the applicant to seek to collect data about patients who chose to receive all or the majority of their diabetes care in primary care setting without seeking their consent.
- The Advisory Group were concerned about proposals to register as many as an additional 200,000 patients who are at increased risk of diabetes or CVDD.
- That the application was not clear on the basis for collecting information on approximately a third of the local population; or whether it was likely that they had been advised by their GPs that they were considered to be at risk of DM/CVD; or what would be done to seek consent from patients after they had been registered.
- That the applicants should seek additional input from patient and user groups. It also recommended that the applicant seek advice from an ethics committee because of concerns that inclusion on the register – without a diagnosis – may have implication for patients.

The Manchester NHS Agency did not change their application for the meeting but did submit two letters in response to the Advisory Group's concerns. The applicant expressed concern that the Advisory Group had approved a similar project and asked that they reconsider their application.

The Advisory Group did not approve the application and requested that the applicants resubmit their application and complete the following:

- That they provide a more detailed explanation of why they are not able to gain patients consent.
- That they provide a more patient focussed approach to the application and in particular:

- By explaining how patient will benefit by the proposed use of their information.
- By involving patients in the design and operation of the register and thereby demonstrating they understand their concern about the use of their personal data.
- By developing an exit strategy, with end dates, away from reliance on Section 60 support to a consent-based approach to collecting and processing data.

ACTIONS: (i) Applicant to be informed of the Advisory Group's decision.

The Confidential Enquiries

4.6 Mr Kirwan explained that the Advisory Group had approved an application from NICE for Section 60 support for the Confidential Enquiries in December last year. NICE had subsequently made a submission to the Advisory Group on progress made in the last 6 months since approval was obtained.

4.7 The Group considered the application and in particular the issues relating to the use of the NHS number. NICE and the Enquiries had undertaken work on the extent to which NHS number is available in Trusts. The outcome of this was that NHS is number is more widely available than is actually being used. The reasons for this were not always clear, however this work demonstrated that the NHS number could be utilised more often than currently. The Group wished to thank NICE and the Enquiries for undertaking this valuable work.

PIAG's Second Annual Report

4.8 The Advisory Group were asked their views on the layout and content of the next annual report. The Group agreed that the layout should be similar to last year's report. Mr Kirwan agreed to have this completed for the December meeting.

ACTION: Mr Kirwan to complete the Second Annual Report for the next meeting.

Future meetings

4.9 The Advisory Group were advised that the Secretariat had asked for availability for proposed dates for next year's meetings. Members agreed to inform the Secretariat of their availability and dates and venues would be confirmed shortly.

4.10 The Advisory Group also agreed to postpone the training day from the December meeting to the March meeting next year. Therefore, member were advised that the next meeting of the Advisory Group would be a Strategic meeting and take place on the 6 and 7 December.

ACTION: Secretariat to confirm dates and venues for meetings in 2005.

5. NHS Care Records Service

7.1 Harry Cayton from the National Programme for IT (NPfIT) was in attendance to discuss the Group's concerns regarding the NHS Care Records Service. Professor Higgins explained that the Advisory Group had written to Aidan Halligan to outline their views from their previous meeting.

7.2 Mr Cayton requested that the Secretariat confirm these concerns and those raised at the meeting in a briefing note to him.

ACTION: Chair/Secretariat to brief Harry Cayton setting out the Advisory Group's concerns and inviting him to discuss them at a future meeting.

8. New Applications for Section 60 Support

8.1 The Advisory Group considered new applications for Section 60 support as follows:

(i) NHS Litigation Authority – Audit of randomly chosen patient records, adverse incident reports and complaints and claims files [PIAG 3-06(b)/2004]

8.2 The Advisory Group considered an application from the NHS Litigation Authority for an audit of patient records, adverse incident reports and complaints and claims files, as part of the NHSLA's assessment of trusts' standards of risk management. Section 60 support was required because the applicants wish to view a random selection of records.

8.3 The Advisory Group approved the application subject to the following conditions:

- That the clinical assessment part of the audit is completed by a registered clinician.
- That patients are informed by posters and leaflets around the hospital that this audit is taking place.
- That they generate a system to ensure that all members of staff will not disclose patient information to others.
- That they commit to improving patient involvement.

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

(ii) Department for Transport – Matching of HES data on road casualties admitted to hospital with data on casualties recorded by the police and compiled by the DfT [PIAG 3-06(c)/2004]

8.4 The Advisory Group considered an application for Section 60 support from the Department for Transport to match data they compile on road casualties with

Hospital Episode Statistics data. Section 60 support was required due to the amount of patient data required.

8.5 The Advisory Group requested that the data matching exercise be completed by the HES team at the Department of Health on behalf of the Department for Transport. This would therefore eradicate the need for Section 60 support as the applicants will not be receiving identifiable patient information.

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

(iii) University of Newcastle Upon Tyne – Pilot study: Long Term sequelae of radiation exposure from computed tomography [PIAG 3-06(d)/2004]

8.6 The Advisory Group considered an application from the University of Newcastle Upon Tyne for Section 60 support for a study into long-term sequelae of radiation exposure from computed tomography. Section 60 support is required as the study requires data about 15,000 exposed individuals dating back over 15 years.

8.7 The Advisory Group approved the application subject to the applicants seeking involvement from patient organisations/representatives.

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

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

8.8 The Advisory Group considered an application from the University of Bristol for Section 60 support for a study of population-based screening for localised prostate cancer in the UK. Section 60 support was required to use data of patients who did not provide their consent for the project.

8.9 The Advisory Group felt unable to approve the application and requested that the applicants provide the following additional information if they wanted to re-submit:

- A more detailed explanation of why they are not able to gain patient consent.
- To clarify the aims of the study in order to justify the use of the data.
- To demonstrate that they will seek involvement from patient organisations/representatives.
- That they do not use identifiable information of those patients who refuse consent.

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

(v) The Institute of Cancer Research, Investigation of referral rates in men with raised Prostate Specific Antigen levels [PIAG 3-06(f)/2004]

8.9 The Advisory Group considered an application for Section 60 support from the Institute of Cancer Research for an epidemiological study to investigate the impact of NHS guidelines for testing prostate cancer on referral rates by GPs. Section 60 support was required as the data was being collected retrospectively and some patients may have moved or died.

8.10 The Advisory Group approved the application.

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

(vi) Cancer Research UK – Population-based study of mortality from Squamous Cell Carcinoma [PIAG 3-06(g)/2004]

8.11 The Advisory Group considered an application for Section 60 support from Cancer Research UK, Melanoma and AMS Study Group to carry out a clinico-pathological case-control study of fatal Squamous Cell Carcinoma to define predictors of mortality. Section 60 support was required as the applicants felt that contacting the patients could worry them unnecessarily. In addition, some of the data required was about deceased patients.

8.12 The Advisory Group approved the application subject to the following condition:

- That the applicants understood that patients' relatives will not be able to provide consent on behalf of the patients.

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

(vii) Cancer Research UK Clinical Centre – Generation of renal and bladder cancer tissue arras for marker/target assay [PIAG 3-06(h)/2004]

8.13 The Advisory Group considered an application for Section 60 support from Cancer Research UK Clinical Centre to use Yorkshire Cancer Registry data to identify and approach patients to seek their consent to use archival tissue samples and information about their cancer. Section 60 support was required to contact the patients to gain their consent for the study.

8.14 The Advisory Group approved the application subject to the following conditions:

- That they re-examine the dataset with a view to reducing the number of identifiable data items collected.
- That they give definite figures on the numbers of patients who provided consent.
- That they commit to improving patient involvement in the study.
- That they have an effective protocol in place to prevent and address the possibility of a breach of patient confidentiality by an employee with only an honary contract.

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

(viii) University of Oxford – Study into the long-term use of aspirin on the risk of colon cancer [PIAG 3-06(i)/2004]

8.15 The Advisory Group considered an application for section 60 support from the University of Oxford for a study titled 'Does the long term use of aspirin reduce the risk of colon cancer'. Section 60 support was required because the study will be linked with another study performed in the 1970's and 1980's and some of the patient's are now deceased.

8.16 The Advisory Group approved the application subject to the following condition:

- That the applicants seek involvement from patient organisations/representatives.

9. Any Other Business

9.1 Mr Kirwan agreed to send a note to members of the Advisory Group explaining why the new GMS contract meant that the regulations made under Section 60 of the Health and Social Care Act 2001 no longer needed to be revised.

ACTION: Mr Kirwan to inform the Advisory Group of why the new GMS contract meant that the regulations made under Section 60 of the Health and Social Care Act 2001, no longer needed to be revised.

10. Date of next meeting

10.1 Future meetings of the Advisory Group were scheduled as follows:

- 6-7 December 2004
- 14-15 March 2005
- 6 June 2005
- 5 September 2005
- 5 December 2005