PATIENT INFORMATION ADVISORY GROUP

Meeting on Monday 9 September 2002

MINUTES

1. **Present**

Members: Professor Joan Higgins (Chair), Dr Michael Catchpole, Professor Sir Cyril Chantler, Dr Tricia Cresswell, Mrs Helen Darracott, Professor Andy Haines, Mr Michael Hake, Ms Barbara Meredith, Ms Helen Miller, Ms Julia Palca, Mrs Shahwar Sadeque, Ms Karen Thomson and Dr Michael Wilks.

In attendance: Dr Patrick Coyle, Professor Martin Severs, Mr Graham Pogson, Mr Phil Walker, Mr Alistair Donaldson, Mr Keith Smith and Mr Sean Kirwan; Mr Neil Paterson and Dr Linda Patterson (for Agenda Item 4); Ms Sandra Kiauka (for Agenda Item 5); Dr Anthony Nowlan and Ms Marlene Winfield (for Agenda Item 6).

2. **Apologies (Agenda Item 1)**

Apologies were received from: Professor Sir Denis Pereira Gray.

3. **Minutes of the last meeting (Agenda Item 2)**

3.1 The minutes of the previous meeting that had taken place on 20 June 2002 (PIAG 3-02/2002) were approved.

4. **Matters arising not covered elsewhere on the agenda (Agenda Item 3)**

4.1 Minutes 4.2 and 5.5: It was reported that briefing papers on Research Ethics Committees and the safeguards introduced by Section 60 had been circulated with the meeting papers. A briefing paper on the role of the Information Standards Board was tabled at the meeting.

4.2 Minute 4.3: It was reported that a representative of the Human Genetics Commission had been invited to address the Advisory Group. Although it had not been possible for a HGC member to attend this meeting of the Advisory Group, it was hoped that arrangements could be made for the next meeting.

4.3 Minute 5.4: Mr Walker reported that the Department of Health was working with Cancer Registries to ensure that they were taking steps to

respond to the confidentiality agenda. The Information Commissioner had made it clear that information about the way personal data was used should be made available at patients' point of contact with the NHS. The Department's draft communications strategy on patient confidentiality, and a paper being prepared on the behalf of cancer registries would deal with these issues and would be considered at the next meeting of the Advisory Group.

4.4 Minute 5.8: Mr Walker reported that the Department planned to issue the code of practice for NHS confidentiality for a public consultation exercise to run from October until December. It was agreed that the Advisory Group should consider the consultation documents at its next meeting.

4.5 Minute 8.6: Professor Higgins reported that she had written to Mr David Lammy, the Parliamentary Under Secretary of State for Health, outlining the Advisory Group's advice on issues relating to access by Hospital Chaplains to information about the religious affiliations of patients. She understood that the advice would be taken into account by DH officials responsible for drafting guidance on chaplaincy issues.

4.6 Minute 5.10: The Advisory Group agreed that it should clarify that it had not endorsed the report prepared by Secta on Options for Pseudonymisation of Patient Identifiable Information, but had accepted that it would make a useful contribution to work in this area.

5. Use of Patient Information by the Commission for Health Improvement (Agenda Item 4)

5.1 The Advisory Group considered a paper that made proposals for the use of patient information by the Commission for Health Improvement [PIAG 3-04/2002]. In addition, Mr Neil Paterson and Dr Linda Patterson, Head of the DH Health Inspection Unit and Medical Director of CHI respectively, gave oral reports.

5.2 It was reported that the Government planned to establish a new body, the Commission for Health Audit and Inspection (CHAI) to bring together the functions of CHI, the private health care role of the National Care Standards Commission and the value for money work of the Audit Commission. Primary legislation to establish CHAI, and a new social care inspectorate – the Commission for Social Care Inspection (CSSI) – would be introduced shortly, and it would be necessary to specify what powers of access to and disclosure of confidential information, including medical records, would be given to CHAI (and CSSI).

5.3 Mr Paterson said that he was seeking advice from the Advisory Group about the access to, and use of, patient information by CHAI. It was important to consider whether or not in some circumstances it would be necessary to give CHAI access to patient identifiable information without the consent of the patient concerned. It was recognised that

robust systems would be required to protect the confidentiality of patients whose information was used in this way.

5.4 Members of the Advisory Group were opposed to allowing CHAI easier access to patient identifiable information. It was felt that the Commission should, above all, be concerned about implementing and promoting good practice – and this would require it to either seek patient consent or use de-identified data.

5.5 Mr Hake, who declared an interest as a member of the Care Standards Commission, stated that there were three basic issues that needed to be borne in mind: firstly that patient/client confidentiality mattered; secondly that inspectorates should only be seeking access to identifiable data when there were protection issues at stake; and thirdly that the interface between health and social care needed close attention.

5.6 Ms Meredith said that it was important to raise the standard of consent taking in the NHS, as the present framework was creating risk and cost to the NHS. She suggested that consideration be given to developing a concept of "consent classes" that recognised that the arrangements for seeking and recording consent to use patient information might vary for different purposes.

5.7 Dr Patterson commented that CHI currently complied with the law. However, there were serious concerns about breaches of patient confidentiality because of failings in the NHS that occasionally led to identifiable data being transmitted to the Commission.

5.8 Dr Cresswell, who acted as a Chair of regional enquiry panels for the Confidential Enquiry into Stillbirths and Deaths in Infancy, stated that where staff had been properly trained it was possible to effectively anonymise records. It may therefore be necessary to provide guidance to the NHS about how data can be anonymised.

5.9 Mr Walker said that for large exercises like those likely to be carried out by CHAI it was preferable that pseudonymised or anonymised data was used, rather than seeking patient consent. He recognised that there may be problems in some parts of the NHS in effectively undertaking these duties. However, one option that might be considered for CHAI could be seeking support under Section 60 of the Health and Social Care Act 2001 for powers to undertake anonymisation of identifiable data itself.

5.10 Mr Paterson said that policy in this area was still in development but that the points made by the Advisory Group would be taken fully into account. He thanked members for their advice.

6. **Diabetes Registers (Agenda Item 5)**

6.1 The Advisory Group considered a paper entitled "National audits and confidentiality" prepared by Diabetes UK [PIAG 3-05/2002]. Ms Sandra Kiauka, the head of audit at Diabetes UK, presented the paper.

6.2 It was reported that Diabetes UK did not represent diabetes registers and had no means of policing their adherence to patient confidentiality and data protection requirements. However, it did manage UKDIABS, a national audit database of adult diabetes services used to assess the level of care provided to patients with diabetes. Although the database aimed to use anonymised data, optional items on the dataset included the NHS Number, date of birth and postcode of each patient. These are used to ensure data quality as some trusts required them to be able to track data back to individuals. Postcode is also used to calculate deprivation scores. Diabetes UK did not have access to the key for NHS numbers. UKDIABS would be wound up shortly when a new dataset had been agreed by NCASP.

6.3 Diabetes UK also worked jointly with the Royal College of Paediatrics and Child Health to carry out the National Paediatric Diabetes Audit. Under these arrangements a UK Children's Diabetes Register had been established. Full information sheets about the register and audit were provided to children and their parents, and informed consent was sought from children aged 12-16 and from the parents of children under the age of 12 for information about them to be collected.

6.4 The Advisory Group agreed that the National Paediatric Audit was a model of good practice. It was suggested that similar activities carried out in the NHS could learn from the audit about how to collect, store and use data about consent.

6.5 With regard to UKDIABS, the Advisory Group noted that efforts were being made towards using wholly anonymised data, but that this was dependent on Trusts' development in this area. However, it was agreed that in the meantime it would be appropriate for Diabetes UK to seek support under Section 60 to collect and store the current UKDIABS dataset.

ACTION: Diabetes UK to apply for Section 60 support to collect and store information in current UKDIABS dataset.

7. **The NHS Confidentiality Workstream (Agenda Item 6)**

7.1 The Advisory Group considered a presentation by Dr Anthony Nowlan and Ms Marlene Winfield, respectively the Director of Stakeholder Relations and the Head of Patient and Citizen Relations at the NHS Information Authority, on the NHS confidentiality Workstream.

7.2 It was reported that the national IT implementation programme for the NHS was focussed on supporting patient care. Key developments

included electronic bookings, electronic prescribing and electronic health records.

7.3 The NHS IA had worked closely with the Consumers Association to carry out qualitative work to find out more about patients' concerns and wishes in these areas. It was clear from this work that patients wanted information integrated around them as individuals rather than at organisation level.

7.4 Ms Winfield reported that the NHS IA would soon be consulting on these issues. She agreed to forward copies of the consultation documents to members of the Advisory Group.

ACTION: Ms Winfield to forward consultation documents to PIAG members.

8. **Applications for Section 60 Support (Agenda Item 7)**

(i) Draft applications for the NHS Wide Clearing Service (NWCS) and the Health Episode Statistics (HES) databases

8.1 The Advisory Group considered two draft applications seeking Section 60 support for the NWCS [PIAG 3-07(a)/2002] and HES [PIAG 3-07(b)/2002] databases. It was reported that final versions of the applications would be submitted for consideration at the Group's meeting in December together with an application for the National Health Authority Information System (NHAIS).

8.2 The Advisory Group welcomed the opportunity to have early sight of these applications. It made a number of comments as follows:

- Neither application had responded adequately to section 3(j) of the application form which sought information about patient and user involvement. More effort had to be made to involve patient groups and NHS service users in the development of national databases such as NWCS and HES. Ms Meredith suggested that the applicants should work with the Patients Forum to educate patients about the activities they carried out and to involve them in the development of their systems.
- The applicants needed to provide more information about third parties who had access to information held in the databases. They needed to ensure that third parties who had access to patient identifiable information had obtained Section 60 support, and to make a stronger statement about the process for passing information to third parties.
- The applications needed to be accompanied by a clear statement from Sir John Pattison, the Department of Health's Director of Research, Analysis and Information, about the process for moving the databases away from their reliance upon identifiable data, with end points and a

commitment to provide the Advisory Group with annual updates on progress.

8.3 It was agreed that the Secretariat should forward these comments to the applicants.

ACTION: Secretariat to forward Advisory Group's comments

8.4 The Advisory Group noted that the databases covered patients in England. Similar systems in Wales would also need to seek Section 60 support.

ACTION: Mr Pogson to advise colleagues in Wales that large databases using patient identifiable data will require Section 60 support.

(ii) Application for the Ataxia-Telangiectasia Society and Cancer Research UK

8.5 The Advisory Group noted that it had considered the application from the AT Society/Cancer Research UK for Section 60 support to collect patient identifiable information for a research study at its previous meeting, but had requested additional information about the purpose of the research and issues relating to IT security.

8.6 As part of a revised application [PIAG 3-07(c)/2002] the applicant had provided a copy of the research protocol for the study and details of Cambridge University's data security policy. However, the Advisory Group remained concerned that insufficient information had been provided to justify Section 60 support being given to use patient identifiable information. In particular:

- The research protocol for the study indicated that the applicant intended to collect and hold patient identifiable information about a great many more individuals than simply the "immediate relatives" of AT patients. It stated that information would be sought about grandparents, aunts and uncles, siblings and also any "more distant relatives" known to have had cancer. The Advisory Group required justification for holding identifiable data about such a wide range of individuals, and an explanation about why after receiving this information it would be impracticable to seek their consent for inclusion in the study.
- Section "h" of the application form: needed to be amended to make it clear that the applicant was seeking "Class Support" to obtain the contact details of patients (or in this case the parents of AT patients) to obtain their consent to participate in the study and, in addition, class support to link data to the NHSCR held by ONS.
- A copy of Cambridge University's Data Protection registration had been provided, but the applicant had not explained how they would abide by this policy (ie - how they would ensure that the database for this study would comply with the requirements of the Data Protection Act).

- Similarly, a copy of the corporate IT security policy for Cambridge University had been provided without explaining how the applicant would ensure that the policy was adequately applied to its systems so that the data was held securely.

8.7 The Advisory Group agreed that the Secretariat should forward its views to the applicant, and that they should be invited to submit additional information in response to the issues identified.

ACTION: Secretariat to invite applicant to submit additional information.

(iii) Application for the All Wales Children's Critical Care Audit

8.8 The Advisory Group considered an application submitted by the All Wales Children's Critical Care Audit [PIAG 3-07(e)/2002] for Section 60 support to use identifiable data in order to monitor the quality of care provided to critically ill children in Wales.

8.9 The Advisory Group raised the following concerns about the application:

- The application stated that the applicant intended to generate a unique identifier for each patient, but did not explain why they could not use the NHS number.
- A list of the full dataset to be held in respect of each patient was required.
- The applicant had not explained what steps they were taking to move away from reliance upon Section 60. This would require them either to develop procedures for obtaining identifiable information with informed consent or to develop pseudonymisation/anonymisation techniques.
- A copy of the Bro Taf HA corporate IT security policy had been provided but the applicant had not explained how it would be applied to their own systems. In addition, because a number of organisations were involved in carrying out activities, the applicant needed to explain who was responsible for custodianship of the data held and how this was managed across all of the organisations involved.

8.10 The Advisory Group agreed that the Secretariat should forward its views to the applicant, and that they should be invited to submit additional information in response to the issues identified.

ACTION: Secretariat to invite applicant to submit additional information.

(iv) Application for the Paediatric Intensive Care Audit Network

8.11 The Advisory Group considered an application submitted by the Paediatric Intensive Care Audit Network (PICANet) [PIAG 3-

07(f)/2002] for Section 60 support to monitor the provision of paediatric intensive care services in England and Wales.

8.12 The application asserted in section 3(i) that one of the reasons that it was impracticable to obtain consent from patients to use their data was that "it may not be a priority for [busy] staff". Although the Advisory Group did not agree that this was an appropriate reason for overriding consent, it was content that the application had provided other evidence that justified the use of identifiable data without consent.

8.13 Mr Donaldson queried the method of data-destruction employed by the applicant and suggested that they contact him for advice in this area.

8.14 However, subject to the applicant acknowledging the issues raised in 8.12 (above) and instigating appropriate measures for data destruction, the Advisory Group agreed that the application should be approved.

ACTIONS: **(i) Secretariat to inform the applicant that the Advisory Group had approved his application for Section 60 support to collect identifiable information so that paediatric intensive care services could be monitored.**
(ii) Details of the application to be entered onto the register of activities carried out with Section 60 support.

(v) Applications from the Institute for Cancer Research and Imperial College

8.15 The Advisory Group considered 4 applications from the Institute for Cancer Research [PIAG 3-07(g)/2002, 3-07(h)/2002, 3-07(i)/2002, 3-07(j)/2002] for Section 60 support to link data with the Office for National Statistics' NHS Central Register. This would allow the records of patients included in cohort studies to be flagged so that when they died researchers would be notified and receive information about the cause of their deaths.

8.16 In addition the Advisory Group also considered 2 applications from Imperial College [PIAG 3-07(k)/2002, 3-07(l)/2002] to link data with the NHSCR so that patients records could be flagged in the same way.

8.17 Mr Smith reported that he had met with ONS official to discuss issues around flagging patient records. He said that around 500 research studies currently had records flagged on the NHSCR so that they could receive notification when patients died or were diagnosed with a particular disease (eg cancer). Since most of these studies had been running for a number of years and some for decades, it would be impracticable for the researchers to retrospectively seek consent from the patients involved. However, ONS was concerned to ensure that it operated within the law.

8.18 The Advisory Group agreed that the applications it had received from the Institute for Cancer Research and Imperial College merited Section 60 support. Each of the studies involved large numbers of patients,

had been running for a number of years, were sponsored by reputable organisations, and were carried out within research governance guidelines.

ACTIONS: (i) Secretariat to inform the applicants that the Advisory Group had approved their applications for Section 60 support to link data with the NHSCR so that individual records can be flagged.
(ii) Details of the applications to be entered onto the register of activities carried out with Section 60 support.

8.19 The Advisory Group received anecdotal evidence that some of the studies that had flagged records on the NHSCR were of limited value, would be unlikely to receive approval under current research ethics arrangements, and would not be able to demonstrate that they met data protection and IT security standards. It agreed that it was important ONS should be able to identify such activities so that, if they were unable to make improvements, they could be required to destroy any identifiable data they held.

8.20 With regard to historic studies that had already flagged records on the NHSCR, the Advisory Group agreed that the ONS should submit a single application to ensure that these activities were carried out within the law. However, its application would need to include safeguards to ensure that each research study was linked to an organisation with a research governance policy, met the requirements of the data protection act, and had appropriate data and IT security arrangements in place.

8.21 The Advisory Group also agreed that organisations undertaking new studies that required NHSCR records to be flagged without consent from the patients involved should be required to apply prospectively for Section 60 support for each study. Also existing research that involved recruiting new patients for inclusion in their studies would be required to either obtain consent from the patients involved or, where this was impracticable, apply for Section 60 support for each study.

ACTION: Advisory Group to communicate the Advisory Group's views to ONS and to invite it to submit a group application to cover all existing flags on the NHSCR database.

(vi) Application from the Northern Region Colorectal Audit Group

8.22 The Advisory Group considered an application from the Northern Region Colorectal Audit Group (NORCAG) [PIAG 3-07(d)/2002]. The application sought Section 60 support to use identifiable data for audit purposes and to flag the NHSCR records of patients involved.

8.23 It was noted that the audit involved processing information for about 1,500 patients each year who had been admitted with colorectal cancer to surgical units in the former Northern region of the NHS.

8.24 Although the Advisory Group recognised that it would be impractical for the applicant to retrospectively obtain consent from each of the patients included in the audit since 1997, it did not agree that it was impractical or inappropriate to seek consent from new patients.

8.25 The Advisory Group was not, therefore, content to approve the application.

ACTION: Secretariat to advise applicant that they should seek consent from patients to be included in the audit and to have their NHSCR records flagged.

9. Date of future meetings (Agenda Item 8)

9.1 The next meeting of the Advisory Group was scheduled to take place on 5 December.

9.2 It was agreed that the Secretariat would circulate to members possible dates for meetings in 2003.

ACTION: Secretariat to circulate possible dates for PIAG meetings in 2003.

10. Any other business (Agenda Item 9)

10.1 The Advisory Group considered a draft outline for a training day. It was proposed that the day would include a presentation on the recent history of confidentiality policy in the NHS, a discussion about the roles of key organisations and individuals in UK confidentiality policy, and issues around the implementation of the confidentiality strategy.

10.2 Members agreed that a training event would be helpful and asked the Secretariat to arrange one to take place on 4 December.

ACTION: Secretariat to arrange training day for PIAG members to take place in London on 4 December.