PATIENT INFORMATION ADVISORY GROUP

Meeting on Thursday 20 June 2002

MINUTES

1. Present

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

In attendance: Mr Patrick Coyle, Dr Grant Kelly, Professor Martin Severs, Mr Graham Pogson, Mr Phil Walker, Mr Alistair Donaldson and Mr Sean Kirwan; Mr Peter Singleton (for Agenda Item 4); Sir John Pattison and Mrs Linda Shurlock (for Agenda Item 5).

2. Apologies (Agenda Item 1)

Apologies were received from: Mr Michael Hake.

3. Minutes of last meeting (Agenda Item 2)

3.1 The minutes of the previous meeting that had taken place on 8 March 2002 (PIAG 2-02/2002) were approved.

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

4.1 Professor Sir Cyril Chantler queried the regulations that had been made under Section 60 of the Health & Social Care Act 2001 in connection with communicable disease surveillance – particularly in relation to support for the creation of a register of all patients at risk of developing vCJD. He understood that if patients would not be told that they were on the register then they should be able to find out. Dr Wilks advised members that the CJD Incidence Panel was still considering this matter, but that it raised issues for the Advisory Group about monitoring changes to activities after PIAG had provided approval. Mr Walker replied that this would be less of an issue once extra resources had been made available to the PIAG Secretariat as it would be able to liaise more closely with those carrying out activities with

Section 60 support. In the meantime it was agreed that members should contact the Secretariat if they had similar concerns or became aware of changes between meetings.

4.2 In relation to minutes 5.8 and 5.18, Ms Meredith requested additional briefing for members on the roles of research ethics committees and the Information Standards Board.

ACTION: Secretariat to prepare briefing papers on RECs and ISB for Advisory Group members.

4.3 Members received a copy of "Inside Information: Balancing Interests in the use of Personal Genetic Data" a summary report by the Human Genetics Commission [PIAG 2-03(a)/2002]. They noted the HGC's concerns about the use of genetic information but that it had also concluded that it is sometimes necessary to use patient identifiable information without consent. It was agreed that a member of the HGC should be invited to address a future PIAG meeting.

ACTION: Secretariat to invite a representative of the HGC to address a future meeting of the PIAG.

5. Progress since last meeting (agenda Item 4)

(i) Section 60 Regulations

5.1 Members received a copy of the Statutory Instrument passed by Parliament under Section 60 of the Health and Social Care Act 2001[PIAG 2-04(a)/2002], and considered Hansard extracts reporting the parliamentary debates on the SI [PIAG 2-04(b)/2001 and PIAG 2-04(c)/2002].

5.2 Mr Walker reported that in approving the regulations contained in the SI, two issues had arisen from the debate in the House of Lords. Firstly, the PIAG and its Chair would be expected to take on a higher public profile. Secondly, there would be a full debate on patient confidentiality in the House of Lords towards the end of the year.

5.3 He also commented that since the regulations had been approved, considerable pressure was building up in the NHS for guidance on how the new arrangements would work. It was anticipated that a great number of organisations would consider submitting applications for Section 60 support, and this would have a significant impact on the Advisory Group and its Secretariat. The Department of Health was putting in place resources to meet these increased demands.

5.4 Sir Cyril Chantler asked how cancer registries would meet the fair processing requirements of the Data Protection Act that sought to ensure that individuals were informed of the fact that organisations held information about them. Mr Walker replied that he would liaise with the Information Commissioner to find out what was required and

would report back to the next meeting. He advised members that the Department of Health was planning for the longer term by devising a communications strategy for NHS staff and patients about how personal information was used.

ACTION: Mr Walker to liaise with Information Commissioner about how cancer registries can meet fair processing requirements of the Data Protection Act.

5.5 Ms Meredith reported that she had received a number of queries about Section 60 from people who did not understand how the new arrangements would work. She requested that the Secretariat should produce briefing material for members setting out how the Section 60 regulations established a code and safeguards for the use patient identifiable information. Members agreed that this would be a helpful document.

ACTION: Secretariat to produce briefing material for use by members.

(ii) Code of Practice on Confidentiality

5.6 Mr Singleton reported that he had been engaged by the Department of Health to develop a code of practice on confidentiality for the NHS. It was designed to resolve the conflicts between the different guidance documents that had been issued by a range of different organisations, and also to act as a driver for change in the NHS by setting out minimum requirements and the staging posts to better practice.

5.7 Members agreed that the code of practice would be a very useful documents for NHS staff, but felt that a significant amount of work would be required before it could be distributed. It was also suggested that it would be helpful for staff if it was accompanied by a shorter document covering the key principles as a document of that type was more likely to be used by staff.

5.8 It was also agreed that the code would require an implementation strategy – particularly if it was to introduce minimum standards for the NHS – in order that the Department of Health could monitor its effect on practice.

ACTIONS: (i) Members to forward written comments on the draft Code of Practice to Peter Singleton.
(ii) Members to contact Secretariat if they wish to become involved in work on developing the Code.

(iii) Draft Report on Options for Pseudonymisation of Patient Identifiable Information

5.9 Members received a copy of a draft report on options for pseudonymisation of patient identifiable information [PIAG 02-

04(d)/2002]. The report had been written by Secta, a consultancy firm appointed by the Information Policy Unit.

5.10 The Advisory Group noted that the report proposed the establishment of an organisation at national level to pseudonymise data. It was recognised that reprocurement of the NHS Wide Clearing Service would offer an opportunity for the development of this service. However, it would be necessary to carry out a risk assessment in order to resolve issues around the accuracy of data.

6. The Status of Large National Databases such as NWCS and NHAIS (Agenda Item 5)

6.1 Professor Higgins welcomed Sir John Pattison, the Department of Health's Director of Research, Analysis and Development, who had been invited to address the Advisory Group on the status of large national databases.

6.2 Sir John said that the Department of Health was responsible for 2 main national databases: the NHS Wide Clearing Service (NWCS) and the National Health Authority Information System (NHAIS).

6.3 The NWCS served a number of key functions:

- Health Episode Statistics (HES) data – and from that the bulk of Department of Health and NHS statistics - was derived from it;
- It was used to support the commissioning of NHS services;
- It was used to support a number of other key functions such as research.

6.4 Sir John reported that NWCS was to be extended to include outpatient as well as inpatient data. Reprocurement of the system was due to begin shortly, and this was seen as an ideal opportunity to consider developing options for pseudonymising information so that patient identifiable data was not disclosed in the future. Such a development would be important if NWCS data was to form the basis of the Health Record Infrastructure that was being put in place to support EHR work.

6.5 In the longer term 3 routes were being considered to ensure that the NWCS work within DPA and common law requirements: by using anonymised data; by seeking consent from patients – although the risk of significant numbers of patients opting out might undermine statistics and research; or to consider introducing legislation.

6.6 The NHAIS was used:

- To identify patients registered with GPs (a statutory function);
- As the basis for calculating part of GPs' remuneration (based on the number of patients registered with them and some of the services they provided);
- For cervical screening and other call-ups;

- To facilitate the exchange of information when a patient moved from one GP to another.

6.7 Sir John added that NHAIS would need to change in order to respond to organisational change within the NHS – particularly HA and primary care structures, and to provide enhanced support for screening services in order that NHS Plan commitments could be met. However, the Department of Health believed that before NHAIS information could be obtained and processed in accordance with the provisions of the Data Protection Act, it would be necessary to commission work to establish exactly how the information was used and how it benefited patients.

6.8 Mr Coyle advised members that the Security and Confidentiality Advisory Group, of which he was the Chair, had been established to oversee the use of patient information held on these databases and to consider applications from third parties for access to it.

6.9 Professor Higgins thanked Sir John for his remarks. She summarised the views of the Advisory Group by stating that it recognised the important role played by NWCS and NHAIS, but thought it was essential that they should be operated in accordance with the provisions of Section 60 until consent and pseudonymisation procedures were implemented. It was therefore agreed that the Department of Health would submit an application for Section 60 support to cover the activities of these databases.

ACTION: Department of Health to submit application for Section 60 support to cover use of patient identifiable information by NWCS and NHAIS.

7. Process for Applying for Section 60 Support to use Patient Identifiable Information (Agenda Item 6)

7.1 The Advisory Group considered a draft guidance note for organisations considering applying for Section 60 support to use patient identifiable information [PIAG 02-05/2002].

7.2 Mr Donaldson said that he would pass his comments to the Secretariat on the security aspects of the guidance and application form. He would propose changes that would seek additional information from applicants that would ensure that the processed and held data as securely as possible.

7.3 It was agreed that the guidance should be made available as soon as these changes had been incorporated. However, it was also recognised that the guidance would change over time with the benefit of experience and as precedence was established.

ACTIONS: (i) Mr Donaldson to advise Secretariat on changes to guidance on data security.

(ii) Secretariat to issue revised guidance note.

8. Access by Hospital Chaplains to Information about the Religious Affiliations of Patients (Agenda Item 7)

8.1 Members considered a paper on chaplaincy in the NHS [PIAG 02-06/2002] and an extract from Hansard [PIAG 02-06(b)/2002]. Professor Higgins reported that Hazel Blears, the Parliamentary Under Secretary of State for Health, had requested PIAG's advice on issues relating to hospital chaplains accessing data about the religious affiliation of hospital patients.

8.2 The Advisory Group recognised that in many hospitals chaplains played a key role within health teams. However, it was agreed that common law and Data Protection requirements were clear: consent should be obtained from patients before details of their religious affiliation were made available to chaplains or before chaplains contacted representatives from other faiths to advise them that a member of their laity had been admitted to hospital.

8.3 In addition, members believed that information about a person's religious affiliation should be regarded as a sensitive data item under the terms of the Data Protection Act 1998, and also that some patients would regard information about their admission to hospital to receive treatment as confidential in itself.

8.4 The Advisory Group drew attention to the fact that most NHS Trusts sought information about the religious affiliation of patients when they were admitted to hospital. In most cases it was therefore possible at the beginning of each care episode to seek consent for this information to be shared with the hospital chaplain or other religious representatives. However, where patients were unconscious or unable to provide consent at admission, then Trusts should seek advice from the patient's family or make a decision in the best interests of the patient.

8.5 Members recognised that the practicalities of changing computer systems might make recording this information difficult it was recommended that this issue should be taken in to consideration when new systems were being procured. In the meantime chaplains should be able to provide information to patients about the services they provide by distributing leaflets and posters or through hospital welcome packs.

8.6 It was agreed that Professor Higgins should forward this advice in a letter to the Minister.

ACTION: Professor Higgins to write to the Minister setting out the Advisory Group's advice.

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

(i) Application from the Manchester Wide Diabetes Register

9.1 The Advisory Group considered an application that had been submitted by the Manchester NHS Agency [PIAG 2-08(a)/2002] for Section 60 support to cover the activities of the Manchester Wide Diabetes Register including regular review and recall of patients, the development of structured care programmes, monitoring of high risk groups, and managing demand and access to services.

9.2 Members did not believe that the application had justified its claim that it was impracticable to obtain consent from patients. They recognised that many diabetes patients have regular contact with the NHS – the application itself claimed that they were seen on an annual basis at the very least – and did not understand why such low consent rates were being reported.

9.3 The Advisory Group agreed that the application should not be approved, and that the applicant should be advised to seek consent from patients.

ACTION: Secretariat to: inform the applicant that application has been rejected, and advise that consent should be obtained from patients.

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

9.4 The Advisory Group considered an application that had been submitted by Dr Douglas Easton for support to use patient identifiable data in a study funded by the Ataxia-Telegiectasia (AT) Society and Cancer Research UK.

9.5 The application stated that evidence suggests that people with AT have an increased incidence of cancer. Although the applicant claimed that "specific" support was required, it appeared that the main requirement was to link new information to existing records obtained as part of a cohort study.

9.6 However, members did not feel that the application adequately described how the research would be conducted and why, therefore, patient information was required. It was agreed that the applicant should be required to submit a copy of the research protocol for the study.

9.7 In addition, Mr Donaldson informed members that he had a number of concerns about the IT security aspects of the application. He agreed to advise the Secretariat of specific issues to which the applicant should be asked to respond.

ACTIONS: (i) Mr Donaldson to advise Secretariat of concerns about security aspects of the application.
(ii) Secretariat to seek copy of research protocol and response on security concerns from the applicant for consideration at the next meeting of the Advisory Group.

(iii) Application from Dr Amber Batata

9.8 The Advisory Group considered an application from Dr Amber Batata for access to anonymised data from cancer registries.

9.9 Members agreed that the data required by Dr Batata was insufficient for patients to be identified. She did not, therefore, require Section 60 support to carry out her study. However, it was noted that in her application she had stated that she required the month and year of birth of patients, but that year of birth alone would be sufficient. It was agreed that she should therefore be advised that she should restrict her data requirements in this respect to year of birth.

ACTION: Secretariat to advise Dr Batata that Section 60 support was not required, but that she should revise her data requirements as described in para 9.9.

(iv) Application from the Office of National Statistics (ONS) and National Evaluation of Sure Start (NESS)

9.10 The Advisory Group considered an application from the ONS and NESS for access to patient identifiable data in order to establish a child health database that could be used to provide aggregated data to NESS about children in Sure Start areas, and to provide statistical analysis and summaries in the wider context of child health.

9.11 Members noted that Section 60 support was requested because it was claimed that the NESS team was working to a tight timescale and budget. This was regarded as a very weak excuse. Members were also concerned that the proposed database would be used to provide information for a number of other undisclosed projects.

9.12 Since parental involvement was a key component of Sure Start, the Advisory Group was disappointed that the applicants had not done more to seek consent – particularly as evaluation of results must be regarded as an integral part of Sure Start.

9.13 In addition, since children under 5 years had regular contact with the NHS – via GPs and Health Visitors – members believed that it was possible to obtain consent for patient information to be used in the way.

9.14 The Advisory Group agreed that the application should not be approved, and that the applicant should be advised to seek parental consent to obtain the child health data required.

ACTION: Secretariat to advise applicant that application for Section 60 support had been rejected and that, instead, consent to collect the information should be obtained.

(v) Application from ONS and the British Isles Network of Congenital Anomalies Registers

9.15 The Advisory Group considered an application for section 60 support to obtain patient identifiable information from the British Isles Network of Congenital Anomalies Registers (BINOCAR). The data would be used to monitor the frequency, nature, cause and outcomes of congenital anomalies through national, regional and disease specific registers of congenital anomalies.

9.16 Before discussion of this application began, Dr Cresswell declared that she had an interest as she was closely involved in the work of the Northern region's congenital anomaly register.

9.17 Members recognised that obtaining consent for information to be collected was difficult: the registers received data from up to 20 different sources, some of which did not have direct contact with the parents of the children involved; it was also acknowledged that it was not always appropriate to seek consent from parents when they were coming to terms with difficult news.

9.18 In addition members noted that the register contained data not just about children with congenital anomalies but also both their parents. This complicated issues around obtaining consent.

9.19 Members also noted that the registers were not uniformly organised – some were regionally based, and some were run under a national umbrella by the ONS – and it was agreed that this was not a satisfactory arrangement.

9.20 Members agreed to recommend that the application should be approved subject to the following conditions:

- That the registers should produce information to be displayed in appropriate places explaining the existence and purpose of the registers and allowing opt-out;
- That within 12 months the applicant should return to the Advisory Group with proposals for obtaining consent to hold information about children and parents;
- That the registers' datasets should be extended to include a specific field for recording whether or not consent had been obtained;
- That the registers should, within 12 months, be working on a uniform basis, preferably through ONS.

9.21 In addition, Mr Donaldson requested that each of the registers should be requested to provide information about their own security arrangements.

ACTIONS: (i) Applicant to be advised that the Advisory Group had approved their application subject to the conditions set out in paras 9.19-9.20 above.
(ii) Details of the applications to be entered onto the register of activities carried out with Section 60 support.

(vi) Application from Professor Michael Langman

9.22 The Advisory Group considered an application from Professor Michael Langman [PIAG 2-08(f)/2002] for Section 60 support for a research nurse to obtain access to patient identifiable data so that it could be anonymised before being entered onto a database.

9.23 Members noted that the application, to support a study entitled "Sudden death in the community: an examination of drug exposure as an antecedent factor", had been considered at the Advisory Group's previous meeting and had been resubmitted with additional information in response to a number of concerns it had had.

9.24 It was agreed that the revised application responded adequately to the issues the Advisory Group had raised previously. Although members were not persuaded by Professor Langman's argument that the research would be biased if patients were allowed to opt-out of the study, members recommended that the application should be approved for the following reasons:

- A degree of patient consent could be implied as information about the research would be displayed in practice waiting rooms;
- It was difficult to obtain consent from many of patients because they were either deceased, near death or confused; and
- The research nurses examining patient records had a contractual obligation of confidentiality.

ACTIONS: (i) Secretariat to inform the applicant that the Advisory Group had approved his application for Section 60 support to allow research nurses to examine patient records in order that anonymised information could be collected.
(ii) Details of the application to be entered onto the register of activities carried out with Section 60 support.

10. Future Meetings of the Advisory Group (Agenda Item 9)

10.1 The next meeting of the Advisory Group was scheduled to take place on Monday 9 September 2002.

11. Any Other Business (Agenda Item 10)

11.1 Ms Meredith commented that the Cabinet Office had issued a consultation document entitled, "Privacy and Data Sharing: The way forward for public services", that covered some issues of relevance to the work of the Advisory Group. It was agreed that copies of the report should be sent to members, with a view to the Advisory Group submitting a response.

ACTION: Secretariat to circulate copies of Cabinet Office consultation document and draft response to members for comment.

11.2 Several members suggested that I would be necessary to examine the way the Advisory Group conducted its business. It was anticipated that the volume of applications for Section 60 support was likely to increase, and that there were a number of issues on the wider confidentiality agenda that would also need to be considered.

11.3 Professor Higgins said that she would discuss these issues with the Secretariat with a view to bringing proposals forward to the next meeting of the Advisory Group.

ACTION: Professor Higgins and Secretariat to make proposals on the organisation of PIAG business.

11.4 Dr Catchpole commented that the Advisory Group had considered several applications for Section 60 support from organisations that had claimed it was impracticable to get consent from patients to use their information for some purposes when an initial investigation or diagnosis was made because they were coming to terms with difficult or sensitive information. Members agreed that this was an issue that merited further consideration as it was essential that organisations developed procedures for obtaining informed consent from patients.

ACTION: Secretariat to draft proposals on obtaining consent from patients coming to terms with difficult or sensitive diagnoses.