PATIENT INFORMATION ADVISORY GROUP

Meeting on Tuesday 10 June 2003

MINUTES

1. Present

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

In attendance: Mr Patrick Coyle, Mr Ian Pepper, Mr Phil Walker, Mr Simon Old, Mr Alistair Donaldson, Mr Peter Singleton, Mr Sean Kirwan. Ms Alison Redwood.

2. Apologies

2.1 Apologies were received from: Ms Julia Palca, Mrs Shahwar Sadeque, Professor Martin Severs.

3. Minutes of last meeting (Agenda Item 2)

3.1 The minutes of the previous meeting that had taken place on 25 March 2003 [PIAG 2-02/2003] were approved.

4. Matters arising/action points (Agenda Item 3)

4.1 Minute 4.2: It was confirmed that Ms Meredith's comments on the Delayed Discharges Bill and the NHSIA consultation on confidentiality had been forwarded to all members.

4.2 Minute 5.5: Mr Walker confirmed that he had had preliminary discussions with the Office for National Statistics about the provision of a postcode mapping service. However, this work had now been added to the NHS National IT Programme.

4.3 Minute 7.7: It was confirmed that the Chair had written to the Secretary of State for Health on 6 May describing the Advisory Group's concerns about powers proposed in the Health and Social Care Bill to allow CHAI and PCTs access to patient records. The letter had been copied to members for information. A response had not

been received in time for the meeting but would be forwarded to members as soon as it became available.

5. Annual Review of Section 60 Regulations (Agenda Item 4)

5.1 The Advisory Group considered a paper on the 2003 annual review of regulations made under Section 60 [PIAG 2-04(a)/2003]. Submissions from the United Kingdom Association of Cancer Registers and the Public Health Laboratory Service were appended to the paper.

Submission by Cancer Registries

5.2 The Advisory Group believed that cancer registries had made significant progress during the last year. The work that had already been undertaken by the UKACR in developing a communications policy to inform patients about the work of cancer registries was welcomed and the Advisory Group looked forward to information materials being made available by April 2003. The Advisory Group also welcomed a data release policy for cancer registries that set out who, and in what circumstances, was able to access patient identifiable information held on the registers.

5.3 The UKACR had also produced a draft policy on data retention and disposal. This how cancer registries should handle requests from patients to delete information about them. The Advisory Group believed that as a general rule cancer registries should take steps to comply with requests to delete information about individuals, but accepted that in some circumstances (eg for very rare conditions) the wider public good might be better served by retaining identifiable data. Although the Advisory Group supported the UKACR's data retention policy, it recommended that cancer registries should handle requests from patients to delete data very carefully.

5.4 The Advisory Group recommended that the UKACR should be required to undertake additional work as follows during the next 12 months:

- That the UKACR should work with ethnic minority groups to test patient information materials
- That input from the Centre for Health Information Quality should also be sought on the design and content of information materials
- That the UKACR should consider the legal issues around obtaining consent from children and their families and produce information materials accordingly
- That cancer registries should aim to make progress in using the NHS number as the key identifier for patients – addressing problems data providers such as laboratories may have in this respect – and be able to provide a firmer date for implementation of this objective.

Submission by the PHLS

5.5 With regard to the submission from the PHLS, the Advisory Group welcomed the work that had been undertaken during the previous year. Although it noted that the progress on implementing the Caldicott requirements had been made, the Advisory Group was disappointed that this had not happened as quickly as desired. However, it

did appreciate that there were problems associated with deleting full postcode from patient records and recommended that pseudonymisation should be pursued as a solution to the problems experienced by the PHLS.

5.6 The Advisory Group noted that the functions of the PHLS had been largely taken over by the Health Protection Agency. Although it was accepted that this change may have had some organisational implications, the Advisory Group hoped that these were restricted to the short-term and that the HPA would place as much emphasis as the PHLS on making improvements in the way patient identifiable information was processed.

5.7 It was noted that the HPA might, in the future, be required to respond to public concerns about new communicable diseases such as SARS. It was agreed that Section 60 should be used to support work in this area, and that if the disease was serious enough, the Section 60 annual review process could be used to recommend legislation to change the status of particular infections so that they would be treated as notifiable diseases.

5.8 The Advisory Group also noted that the HPA would have a wider remit than the PHLS and that it would soon assume responsibility for chemical and radiological protection issues. It was agreed that although regulations made under Section 60 were broad enough to support work in these areas, the HPA should be required to submit a paper to PIAG before processing patient identifiable information without consent.

Class Support Regulations

5.9 The Advisory Group considered advice from the Secretariat on how the class support regulations should be reviewed. It was agreed that each activity carried out with class support should be reviewed on the anniversary of the original application receiving PIAG approval. The Secretariat would use these reports to compile a single annual submission to PIAG on progress made by organisations. However, it was agreed that where an organisation reported that the conditions of its Section 60 support had been breached or it had failed to make significant progress to limit the use of patient data without consent then the Secretariat should seek advice from the Group on whether further action was required in the interim.

5.10 Overall, the Advisory Group agreed that the regulations made under Section 60 in June 2002 were still required.

ACTIONS: **(i) Secretariat to inform UKACR and HCA of outcome of the annual reviews, including action to be taken by each during the next 12 months;**
(ii) Secretariat to seek submissions from individuals and organisations conducting activities under the Section 60 class support arrangements to inform the annual review process.

6. Draft Regulations to be made under Section 60 (Agenda Item 5)

6.1 The Advisory Group considered draft regulations to be made under Section 60 to support national databases established to support the management of healthcare services in England and Wales [PIAG 2-05(a)/2003].

6.2 It was agreed that safeguards needed to be incorporated into the regulations to prevent abuse of the proposed powers. It would be important to reshape the regulations so that measures to restrict misuse of the powers were set out more explicitly, and the process for approving the creation of databases was strengthened by ensuring that all proposals had to be approved by both the Secretary of State for Health and PIAG.

6.3 The Secretariat explained that after the regulations had been redrafted to take account of the Advisory Group's views, the Department would need to consult more widely on the proposals over a 3 month period. A final draft of the regulations would take account of comments received during the consultation exercise, and would be circulated to PIAG members for approval before being submitted to Parliament.

ACTIONS: (i) Secretariat to incorporate the Advisory Group's comments into the draft regulations;
(ii) Secretariat to arrange public consultation on the draft regulations.

7. PIAG Annual Report (Agenda Item 6)

7.1 The Advisory Group considered a paper proposing the format and content of the Advisory Group's first Annual Report [PIAG 2-06(a)/2003].

7.2 The proposed format was approved. It was agreed that the Report should also explain that the Advisory Group was a learning organisation, and describe areas where it had developed its thinking. The Report should also include a list of all Section 60 applications that had been approved by the Advisory Group.

7.3 The Secretariat agreed to prepare a first draft of the Annual Report for consideration by members by the end of July.

ACTION: Secretariat to prepare draft Annual Report for distribution to members by end of July.

8. Previous Applications for Section 60 Support – Additional Information (Agenda Item 7)

8.1 The Advisory Group considered responses from organisations and individuals whose applications for support under Section to process patient identifiable information without consent had been considered at the Advisory Group's last meeting on 25 March [PIAG 2-08(a)/2003] as follows:

(i) Professor Adam Timmis

8.2 Professor Timmis had sought Section 60 support to process patient identifiable information for a research study to examine outcomes of patients attending rapid access chest pain clinics. The Advisory Group had agreed to approved the application subject to Professor Timmis submitting an appropriate data security policy.

8.3 Mr Donaldson advised the Group that the security policy submitted by Professor Timmis was out of date – it referred to NHS organisations that no longer existed, and was also inadequate as it was a corporate document without information about system level security. It was agreed that Professor Timmis should be required to submit a revised security policy.

ACTION: Secretariat to obtain revised security policy from Professor Timmis.

(ii) West Midlands Perinatal Institute

8.4 The Advisory Group had considered an application from the West Midlands Perinatal Institute for Section 60 support to collect information for work to be carried out within the region to support the Confidential Enquiry into Maternal and Child Health. However, the application had been rejected because the Advisory Group preferred work in this area to be support by a single national application from CEMACH.

8.5 Mr Jason Gardosi, the Director of the West Midlands Perinatal Institute had requested that the Advisory Group should reconsider its decision as a delay in considering an application from CEMACH could damage work being conducted in the West Midlands.

8.6 The Secretariat explained that it had discussed the prospect of CEMACH submitting an application for Section 60 support and it was possible that this would be done in time for the Group's September meeting.

8.7 The Advisory Group agreed to provide interim Section 60 support for the WMPI to collect patient data until the end of December 2003. After that date it would be required to collect data with patient consent or under the terms of any Section 60 support resulting from the expected CEMACH application.

ACTION: Secretariat to advise Mr Gardosi of the Advisory Group's decision.

(iii) Professor Julian Peto

8.8 Professor Peto had received Section 60 support at the last meeting to for a research study to identify occupations and work practices with the highest risk of mesothelioma. However, he had requested that he should be allowed to contact patients directly rather than via their GPs in order to seek their consent to collect identifiable information for the study.

8.9 The Advisory Group agreed that it was important that it should stand by its original decision. It took issue with Professor Peto's assertion that it was sufficient for GPs to provide consent for researchers to contact their patients and maintained that the principle of patients being contacted only by clinicians with which they had a direct relationship was an important one.

8.10 It was also agreed that the Secretariat should write to the MRC to explain the Advisory Group's thinking in this area so that the cost of contacting patients in this way could be factored into research budgets in the future.

ACTIONS: **(i) Secretariat to write to Professor Peto explaining the Advisory Group's decision;**
(ii) Secretariat to write to MRC to explain the principle established by PIAG that consent should be obtained by clinicians with which patients had a direct relationship.

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

9.1 The Advisory Group considered a number of applications for support under Section 60 of the Health and Social Care Act 2001 to process patient identifiable information without consent as follows:

(i) National Clinical Audit Support Programme

9.2 The Advisory Group considered an application from the Department of Health for Section 60 support to cover the National Clinical Audit Support Programme (NCASP) [PIAG 2-08(b)/2003].

9.3 The Advisory Group recognised that NCASP was an important strand of work and were very supportive of its aims. It also recognised that NCASP had been leading the way in developing pseudonymisation techniques and the Group was keen to support and encourage efforts in this direction.

9.4 However, the Advisory Group was very concerned about the assertion made in the application that implied consent could be a sufficient basis upon which patient identifiable information should be processed in the future. The Group felt that the position of the Information Commissioner was not as clear as had been presented, and that the Commissioner was unlikely to have understood the complexity of clinical audit arrangements that exist within the NHS and that the task of making these understood to patients would require significant efforts before any form of consent could be implied. The Advisory Group was of the view that the longer term goal should be for NCASP work to use anonymised or pseudonymised data only.

9.5 In the interim, the PIAG agreed that NCASP audits should be allowed to continue with Section 60 support, but required the following conditions to apply:

- That NCASP should move within 12 months to reliance upon the NHS Number as the key identifier for patients within those audits that were already part of the programme (ie those audits listed in Section 2(e) of the application)
- That NCASP should seek PIAG approval to add new audits to the programme
- That the NHS number should be the only patient identifier used for new audits added to the programme in the future

9.6 The Advisory Group was concerned about the apparent proliferation of large national databases of patient information that to a large extent duplicated one another (for example, for cancer). In particular the Group was very concerned about collection of full postcode for each patient. It was therefore proposed that for those audits where geographical analysis was required that NCASP should seek as far as possible to use aggregated data from an existing dataset rather than collect full postcode. Proposals

for addressing this were required with the aim of eliminating, as far as is practicable, the need to hold full postcode data by the end of the 12 month period.

9.7 NCASP would be required to report to the Advisory Group progress in achieving these objectives under the requirements of the Section 60 annual review process.

9.8 In addition, the Advisory Group also sought additional information on IT security issues as follows:

- That the PIAG Secretariat be provided with a copy of the system-level security policy planned for August 2003
- An explanation of the data retention and destruction policy for NCASP

ACTIONS: (i) Secretariat to inform the applicant of the conditions set for Section 60 support of NCASP;
(ii) Details of NCASP to entered onto the register of activities carried out with Section 60 support.

(ii) NHS "Look-Back" Exercises

9.9 The Advisory Group considered a request for advice from the Department of Health on the use of patient identifiable data for "look-back" exercises [PIAG 2-08(c)/2003].

9.10 It was agreed that it was legitimate for patient information to be processed with out Section 60 support where the aim of a look-back exercise was to identify patients in order to offer them counselling and direct health care for a condition or disease they may already have contracted, or be at a high risk of contracting in the future.

ACTION: Secretariat to inform the Department of Health of the Advisory Group's advice.

(iii) Dr Huw Thomas

9.11 The Advisory Group considered an application from Dr Huw Thomas to obtain details about the health authority registration of a small number of patients who had consented to be part of cohort of patients with familial risk of colorectal cancer [PIAG 2-08(d)/2003]. These patients had been lost to follow-up and Dr Thomas wished to contact them so that they could be offered colonoscopic screening and be invited to provide consent so that their NHSCR records could be flagged.

9.12 The Advisory Group agreed that Section 60 support was not necessary since the patients involved had already consented to be a part of the cohort group, and the applicant wished to contact them so that they could, in part, be offered direct health care.

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

(iv) Manchester University

9.13 The Advisory Group considered an application from Manchester University for a prospective study to investigate management of elderly women attending breast units in Greater Manchester [PIAG 2-08(e)/2003]. The application sought access to identifiable data in order to conduct a randomised response bias analysis.

9.14 The Advisory Group noted the Chair's comments that although she was employed by the University of Manchester and was also Chair of Christie Hospital NHS Trust she had no interest in the application.

9.15 The Group agreed that the activity proposed by the applicant was unlikely to add significant value to the study, and suggested that it would be possible to conduct a similar analysis of response bias by seeking aggregated demographic data from breast units covered by the study. The application was therefore rejected.

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

(v) National Confidential Enquiry into Peri-Operative Deaths

9.16 The Advisory Group considered an application from NCEPOD for Section 60 support for a study on medical admissions into critical care [PIAG 2-08(f)/2003]. The application covered the use of identifiable patient information for patients who had died or received intensive care.

9.17 The Advisory Group was concerned that the nature of confidential enquiries meant that any findings from the study relating to the provision of care to patients who were still alive could not be made available to the courts. It was therefore agreed that the applicant should be required to obtain legal advice to justify the use of data about living patients in confidential enquiries.

9.18 The Group also agreed that it was important that the National Institute for Clinical Excellence should be required to draw up strict criteria for the conduct of confidential enquiry work.

ACTIONS: (i) Secretariat to require NCEPOD to obtain legal advice on its proposed use of data about living patients.
(ii) Secretariat to write to NICE seeking clearer guidance on the use of data about living patients in confidential enquiries.

(vi) Professor Adam Timmis

9.19 The Advisory Group considered an application from Professor Adam Timmis for support for study to analyse baseline variables and outcomes of 3500 patients admitted to three East London Hospitals between January 2000 and December 2001 [PIAG 2-08(g)/2003].

9.20 The application described a database that had already been established and used for analysis work, but the Advisory Group was unsure of the status of this work but noted that the application stated that there had been "no active patient participation". It was agreed that the applicant should have been required to obtain informed consent from patients for any research that had already taken place, and that it would not be appropriate to allow the research to continue with Section 60 support.

ACTION: Secretariat to advise the applicant to seek informed consent from patients to continue research.

(vii) Dr David Ducker

9.21 The Advisory Group considered an application from Dr David Ducker for support for the Census of Neonatal Care in the South East Thames Region [PIAG 2-08(h)/2003]. It was noted that the census database included 60,000 historic records, that new data was collected on the basis of implied consent as parents were given information materials about the census, and that the functions carried out by the census would be transferred to neonatal managed networks within 2 years.

9.22 The Advisory Group was assured that there were adequate IT and data protection arrangements in place, and that the Section 60 support sought by the applicant was to cover the interim until functions were transferred to a local neonatal network. It therefore approved the application, subject to new data being collected with informed consent.

ACTIONS: (i) Secretariat to inform the applicant of the conditions set for Section 60 support;
(ii) Details of the application to entered onto the register of activities carried out with Section 60 support.

(viii) Medical Care Research Unit, University of Sheffield

9.23 The Advisory Group considered an application from the Medical Care Research Unit of the University of Sheffield for a research study into the costs and effects of the implementation of new ambulance response time standards [PIAG 2-08(i)/2003]. It was noted that the study involved 20,000 patients, and the applicant wished to flag these on the NHS Central Register for death notification purposes.

9.24 The Advisory Group also noted that the study had been conducted with ethical approval and had begun before Section 60 had been introduced. It was content that appropriate IT and data protection arrangements had been established and therefore approved the application.

ACTIONS: (i) Secretariat to inform the applicant of that Section 60 support had been granted;
(ii) Details of the application to entered onto the register of activities carried out with Section 60 support.

10. Any Other Business (Agenda Item 9)

10.1 The Advisory Group agreed that the following issues had been identified as key principles during the meeting:

- That clinical care follow-up was not a Section 60 issue
- That decisions about the use of personal data should be taken by patients not by clinicians acting on their behalf
- That data should be anonymised by individuals and organisations that had obtained it directly from patients. It would be helpful to develop guidelines and an accreditation process for those undertaking work to anonymise information.

10.2 In addition, the following issues had been identified as areas where organisations and individuals processing patient information should be required to act with sensitivity:

- The retention of "deleted" data for audit purposes

11. Date of Next Meeting

11.1 The Advisory Group noted that future meetings had been scheduled as follows:

- Monday 15 September 2003
- Tuesday 9 December 2003