PIAG
4-02/2003

PATIENT INFORMATION ADVISORY GROUP

Meeting on 15 September 2003

MINUTES

1. Present

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

In attendance: Mr Patrick Coyle, Mr Phil Walker, Mr Peter Singleton, Mr Sean Kirwan and Ms Alison Redwood.

2. Apologies

Apologies were received from: Professor Andy Haines, Mrs Helen Miller, Ms Karen Thomson, Professor Martin Severs and Mr Alistair Donaldson.

3. Minutes of last meeting

3.1 The minutes of the previous meeting [PIAG 3-02/2003] that had taken place on 10 June 2003 were approved.

4. Matters arising/action points

Revised Section 60 Regulations

4.1 Mr Kirwan reported that progress had been made in preparing revised regulations to be made under Section 60 to provide support for national databases of patient information as agreed at previous meetings of the Advisory Group. Although legal advice had stated that consultation on the new regulations could take place over a shortened period, the Advisory Group agreed that a 3 month consultation was necessary.

ACTION: Secretariat to arrange a 3 month consultation on the revised Section 60 regulations.

Information Governance

4.2 The Advisory Group sought an update on progress to develop guidelines on anonymisation. Mr Walker reported that this work would be taken forward by the Department of Health's Information Governance team, but that it had been delayed by the Department's reorganisation. He agreed to report back to the next meeting.

ACTION: Mr Walker to report progress on the development of NHS guidelines on anonymisation to the next meeting of the Advisory Group.

4.3 Members of the Advisory Group expressed concern that the National Programme for IT (NPfIT) did not include adequate provision for confidentiality issues. These concerns were heightened because the programme specification remained confidential. Although Mr Walker reassured the Group that information governance was one of the largest components of NPfIT it was agreed that Mr Richard Granger, the Director General of NHS IT, should be invited to discuss this work at the Advisory Group's next meeting.

ACTION: Secretariat to invite Mr Richard Granger to the next Advisory Group meeting.

Chair's Action

4.4 It was reported that the Chair had taken action to approve an application that had been considered by the Advisory Group at its March meeting [Professor Timmis and colleagues at Westminster PCT (PIAG 1-08(g)/2003) for a research study into outcomes of patients attending rapid access chest pain clinics]. Approval had been given at that meeting subject to the applicant providing an appropriate system level security policy – which he subsequently did.

4.5 The Advisory Group approved the use of Chair's Action.

5. PIAG Annual Report

5.1 The Advisory Group considered a revised draft of the PIAG Annual Report [PIAG 3-04(a)/2003], and an analysis of Section 60 Applications [PIAG 3-04(b)/2003] for inclusion in the Annual Report.

5.2 Members of the Group were pleased with the format and content of the Annual Report, but suggested the following amendments:

- That the section describing the "principles" developed by the Advisory Group should include the requirement that organisations seeking Section 60 support should build patient/carer involvement into their processes
- That the report should include a glossary of terms and acronyms

5.3 It was also agreed that members should forward any additional comments they had on the report to the Secretariat by the end of September, and that the report should be published by the end of October.

ACTIONS: **(i) Advisory Group members to forward amendments to the Secretariat by the end of September;**
(ii) Secretariat to complete the Annual Report and publish by the end of October.

6. Guidance to Applicants for Section 60 Support

6.1 The Advisory Group considered a revised draft guidance note for organisations/individuals seeking Section 60 support to process patient identifiable information without consent [PIAG 3-05/2003].

6.2 Peter Singleton explained that the guidance note aimed to describe the activities that were appropriate for Section 60 support, and to prevent unnecessary applications by explaining the circumstances in which Section 60 would be an inappropriate means of processing patient information.

6.3 The Advisory Group welcomed the draft guidance note as a helpful document. However, a number of changes were proposed as follows:

- That the guidance note should explain why it was important for applicants to involve patients/services users in the development of their work;
- That the guidance should instruct all applicants to have appropriate data archiving and destruction policies;
- That the guidance should list the Caldicott principles in order to assist applicants in completing Section 4(k) of the application form;
- That the guidance should remind all applicants that Section 60 was an interim measure and consequently all organisations should build consent/anonymisation solutions into their future plans.

6.4 It was agreed that the guidance note should be revised as quickly as possible and made available to applicants via the Department of Health website.

ACTION: **Mr Singleton to amend the guidance note and Secretariat to post on DH website.**

7. NHS Number and the EC Data Protection Directive

7.1 The Advisory Group considered a paper, "Recommendations of the Health Records and Data Protection Review Group on use of the NHS Number", [PIAG 3-06/2003].

7.2 The Review Group had concluded that the NHS number was a general identifier as defined by the EC Data Protection Directive, and it would therefore be important to describe the circumstances in which the NHS number could be used.

7.3 The Advisory Group was concerned that non-NHS organisations (eg Social Services departments, police, education services) that wished to use the NHS number did not have the same rigorous confidentiality policies in place. It agreed that it would be preferable for use of the NHS number to be restricted to health purposes and if this

was not to be the case then the same duty of confidence should be required of all agencies – ideally with Caldicott compliance.

7.4 While the Advisory Group agreed that it was important to distinguish between the use of the NHS number and the use of confidential patient information, it agreed that it was inevitable that any organisation seeking to use the NHS number as a unique identifier would also require access to the NSTS in order to verify the validity of the number. Although the NSTS did not hold patient data, it did include details of the contact individuals had had with NHS organisations – with potential consequences for patient confidentiality.

7.5 The Advisory Group supported the recommendation of the Review Group that processing of the NHS number should be legitimate only where an organisation provides a service as a statutory obligation under the 1977 Health Service Act.

7.6 Members of the Advisory Group expressed concern that the Government consultation paper on child protection, "Every Child Matters", could have consequences for some of these issues. It was therefore agreed that the Advisory Group should consider the paper at its next meeting and participate in the consultation exercise.

ACTION: Secretariat to circulate copies of "Every Child Matters" to members of the Advisory Group and to draft a response for consideration at the next meeting.

8(a). Chlamydia Screening & Disaggregate KC60 Reporting

8.1 The Advisory Group considered a submission from the Health Protection Agency on chlamydia screening and disaggregate KC60 reporting [PIAG 3-07(a)/2003].

8.2 Although the regulations made under Section 60 governing communicable disease surveillance were sufficient to allow the HPA to undertake the work described in its submission, it sought views from Advisory Group on the proposals as they were of a particularly sensitive nature.

8.3 The Advisory Group was advised that patients participating in the chlamydia screening programme received an information leaflet and a self-completion questionnaire. Dr Catchpole reported that potentially patient identifiable data was destroyed after 2-3 years, and that all data was destroyed after 5 years.

8.4 The Advisory Group agreed that it was necessary to consider the patient information leaflet and clarify whether it adequately explained patients' opt-out rights. It was agreed that the Chair could approve the HPA's request to proceed with chlamydia screening on the Advisory Group's behalf, providing she was content that the information available to patients was adequate.

ACTION: Secretariat to obtain patient information leaflet for consideration by the Chair.

8(b). Addition of Outpatient Data to the HES Data Warehouse

8.5 The Advisory Group considered a paper from the Department of Health on the addition outpatient data to the HES database [PIAG 3-07(b)/2003].

8.6 The paper described how it was intended to extend the HES dataset to include outpatient information, in order to improve the quality of data available about the provision of services by the NHS. The proposal to collect this additional data was in line with the recommendations of the Kennedy report that it was important to collect procedure information regardless of the setting in which it had taken place.

8.7 Although the Advisory Group did not agree with the assertion in the submission that it was as difficult to obtain consent from patients receiving outpatient care as it was for those who had been admitted to hospital, it did agree that it was impracticable for HES to obtain consent for the 40 million outpatient episodes that took place annually and recognised that it was not yet possible for only anonymised or pseudonymised data to be processed. The request to extend the HES data warehouse to include outpatient data was therefore approved.

9. The Confidential Enquiries

9.1 The Advisory Group considered a submission from the National Institute for Clinical Excellence on process for obtaining Section 60 support for the Confidential Enquiries [PIAG 3-08/2003].

9.2 The submission had been written following concerns expressed by the Advisory Group at its previous meeting relating to new work by the Confidential Enquiries to investigate serious adverse incidents that patients had survived.

9.3 The submission explained the roles of the different Confidential Enquiries, explained that the National Institute for Clinical Excellence would work with the Enquiries to draw up guidelines within which they should operate and which would be used as the basis for formal applications for Section 60 support to be submitted to the next meeting of the Advisory Group. The submission also included legal advice that had been obtained by NICE on the consent and data protection issues relevant to the Enquiries, and sought interim Section 60 support to allow the Enquiries to continue processing information pending consideration of their formal applications.

9.4 The Advisory Group agreed that it was particularly concerned that that the submission failed to address issues around patient consent. There needed to be a very strong justification for overriding the right of patients to decide whether or not their personal data should be considered by the Enquiries and this had not yet been provided. The submission also failed to consider the implications of the consultation paper, 'Making Amends', issued in June by the Chief Medical Officer which recommended a "duty of candour requiring clinicians and health service managers to inform patients about actions which have resulted in harm". The Advisory Group was therefore concerned that it may be both unethical and illegal for the Confidential Enquiries to continue to process patient identifiable information without consent.

9.5 Although the Advisory Group was concerned to ensure that Section 60 powers are used appropriately, it also wished to be reassured that any organisation or

individual processing patient identifiable data with Section 60 support did so within the requirements of the Data Protection Act – and therefore required evidence that this was the case. The legal advice that had been obtained by NICE therefore needed to be reconsidered, since statements that "PIAG may be operating under a misapprehension about the nature of the laws of confidentiality and data protection" were unhelpful and incorrect.

9.7 However, the Advisory Group was content to allow the Confidential Enquiries to continue processing patient identifiable information while they worked with NICE to develop a code within which they should operate pending submission of formal applications being submitted to the next meeting on 9 December.

ACTION: Secretariat to inform NICE of the Advisory Group's views on its submission and to confirm that the Confidential Enquiries had been given interim Section 60 support until December 2003.

10. New Applications for Section 60 Support

10.1 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) Special Hospitals Case Register

10.2 The Advisory Group considered an application from Mr Martin Butwell for Section 60 support for the Special Hospitals Case Register [PIAG3-09(b)/2003].

10.3 The application explained that the Register was used to Register to support epidemiological and clinical research on patients referred and admitted to Special Hospitals (Broadmoor, Rampton and Ashworth).

10.4 However, although the Advisory Group agreed that the register was used to support important research and possibly required some short-term Section 60 support, it could not approve the application as it lacked some important detail and contained a number of ambiguous statements. It was agreed that the Secretariat should meet with the applicant to discuss the register and its requirements in more detail, with a view to submitting a future application.

ACTION: Secretariat to meet with the applicant to discuss possibility of submitting a revised application.

(ii) Research study of treatment effect and endocrine, genetic and cellular risk factors for contralateral primary breast cancer in women

10.5 The Advisory Group considered an application from Professors Peto and Swerdlow for a research study of treatment effect and endocrine, genetic and cellular risk factors for contralateral primary breast cancer in women [PIAG 3-09(c)/2003].

10.6 The application explained that the research involved a population-based study of the effects of treatment, familial incidence, hormone levels and genetic susceptibility on secondary breast cancer. Section 60 support was required in order to

obtain patient contact details so that their consent for inclusion in the study could be obtained.

10.7 The Advisory Group agreed that the applicant had established appropriate safeguards for processing, archiving and destroying data, and approved the application.

ACTIONS: (i) Secretariat to inform the applicant of the Advisory Group's approval;
(ii) Details of the application to be entered onto the register of activities carried out with Section 60 support.

(iii) Melanoma follow-up and case control study

10.8 The Advisory Group considered an application from Dr Julia Newton Bishop for the melanoma follow-up and case control family study [PIAG 3-09(d)/2003].

10.9 The application stated that the research would investigate factors associated with melanoma and melanoma relapse. Section 60 support was required to obtain patients details in order to obtain consent for inclusion in the study.

10.10 The Advisory Group agreed that the applicant had established appropriate safeguards for processing, archiving and destroying data, and approved the application.

ACTIONS: (i) Secretariat to inform the applicant of the Advisory Group's approval;
(ii) Details of the application to be entered onto the register of activities carried out with Section 60 support.

(iv) EPIC-Oxford Study

10.11 The Advisory Group considered an application from Dr Timothy Key for the European Prospective Investigation into Cancer and Nutrition Oxford Cohort (EPIC-Oxford) [PIAG 3-09(e)/2003].

10.12 The application explained that it was a cohort study to examine the links between dietary factors and the risk of developing cancer. Section 60 support was required in order to link information on 60,000 patients to cancer registry data.

10.13 The Advisory Group agreed that before the application could be approved, the additional information was required as follows:

- That Dr Tim Key should confirm, as research lead, that he would act as Information Custodian for the study;
- That the applicant should provide a written explanation of how they would comply with the principles of the Data Protection Act;
- That the applicant should implement an appropriate data archiving and destruction policy.

ACTION: Secretariat to advise the applicant that additional information was required before approval for the EPIC study could be given.

(v) Research to assess the importance of the location of cancer diagnoses to power lines

10.14 The Advisory Group considered an application from Professor Alan Preece for a study to assess the importance of the location of cancer diagnoses to power lines in terms of proximity and direction [PIAG 3-09(f)/2003].

10.15 The application explained that the study aimed to assess the importance of the location of cancer diagnoses addresses to power lines. Section 60 support was required to allow geographical analysis by postcode to be undertaken.

10.16 Although the Advisory Group did not agree with an assertion in the application that it would be an "unacceptable request" to seek patient consent. However, it did agree that it was currently impracticable to obtain consent from more than 25,000 patients. The application was therefore approved on that basis.

ACTIONS: (i) Secretariat to inform the applicant of the Advisory Group's approval;
(ii) Details of the application to be entered onto the register of activities carried out with Section 60 support.

(vi) Collection of data on patients receiving radiotherapy in the UK

10.17 The Advisory Group considered an application from Dr Brian Cottier for a central collection of data on patients receiving radiotherapy in the UK [PIAG 3-09(g)/2003].

10.18 The application explained that the data would be linked to other data sources and used for geographical analysis and audit purposes. It argued that it was impracticable to obtain consent from patients at a time when they were coming to terms with a difficult diagnosis.

10.19 Although the Advisory Group had no objections to the proposed use of data, it expressed concern about the proliferation of applications seeking to establish national datasets about patients with cancer. It was agreed that Professor Mike Richards, the National Director for Cancer, should be invited to discuss this issue at the next PIAG meeting.

10.20 The application was approved for an initial 12 months, on the understanding that after that time the information could be obtained, in pseudonymised form, from HES as it was being extended to include outpatient data.

ACTIONS: (i) Secretariat to inform the applicant of the Advisory Group's approval;
(ii) Details of the application to be entered onto the register of activities carried out with Section 60 support.

(vii) Data collection for use in the development of Cancer Service Guidance

10.21 The Advisory Group considered an application from Dr Brian Cottier for support to collect data for use in the development of Cancer Service Guidance [PIAG 3-09(h)/2003].

10.22 The application explained that identifiable information was not required, but that the aggregated data sought from the ONS was likely to include "small numbers" data that would technically make it possible to identify individuals.

10.23 The Advisory Group agreed that the applicant had established appropriate safeguards for processing, archiving and destroying data, and approved the application.

ACTIONS: (i) Secretariat to inform the applicant of the Advisory Group's approval;
(ii) Details of the application to be entered onto the register of activities carried out with Section 60 support.

(viii) Research to develop a methodology for the identification of patients in primary care with a diagnosis of cancer

10.24 The Advisory Group considered an application from Shane Pascoe for research to develop a methodology for the identification of patients in primary care with a diagnosis of cancer [PIAG 3-09(i)/2003].

10.25 The application explained that the study would be used to establish a methodology for PCTs to generate a clinical dataset that identifies cancer patients. It was impracticable to obtain patient consent as the research team would need to contact all patients covered by the practice (50-100,000) even though less than 6% would have a cancer diagnosis.

10.26 The Advisory Group agreed to approve the application, subject to the provision of an appropriate system level IT security policy.

ACTION: Secretariat to seek system level IT security policy from the applicant.

(ix) Study to identify and map new genes predisposing to breast and colon or breast and thyroid cancer

10.27 The Advisory Group considered an application from Professor Shirley Hodgson for a study to identify and map new genes predisposing to breast and colon or breast and thyroid cancer [PIAG 3-09(j)/2003].

10.28 The application explained that Section 60 support was required in order to obtain patient contact details so that their consent could be obtained for participation in the study.

10.29 The Advisory Group agreed that it could not approve the application until additional information had been submitted as follows:

- That the applicant explained in more detail how they wouldl comply with each of the 8 principles of the Data Protection Act;
- That a system level IT security policy be submitted;
- That an explantion of how long the applicant intended to retain patient identifiable information be provided;
- That an appropriate data destruction policy be implemented;
- That the applicant explained their corporate IT arrangements (a corporate NHS IT policy had been submitted but the application stated that they were connected to JANET – a university network).

ACTION: Secretariat to seek additional information from the applicant.

(x) Study on the long-term risks associated with the use of proton pump inhibitors

10.30 The Advisory Group considered an application from Professor Paul Moayyedi research study on the long-term risks associated with the use of proton pump inhibitors [PIAG 3-09(k)/2003].

10.31 The application explained that Section 60 support was required to analyse historic data from 1970-1990 – many patients will have died or be lost to contact. In addition the applicant was not seeking to process or obtain patient identifiable information – this would be done on their behalf by the ONS, HES and NHS hospital trusts.

10.32 The Advisory Group did not agree with the applicant that patient/user involvement in the development of the study was not possible, since although there may not be any specific patient organisations for dyspepsia/indigestion or PPI users, there were a number of generic patient bodies that could have provided advice. However, on the basis of other information provided the Group approved the application.

ACTIONS: (i) Secretariat to inform the applicant of the Advisory Group's approval;
(ii) Details of the application to be entered onto the register of activities carried out with Section 60 support.

(xi) Development of disclosure control methodology

10.33 The Advisory Group considered an application from the Office for National Statistics to use HES data for the development of disclosure control methodology [PIAG 3-09(l)/2003].

10.34 The Advisory Group agreed that because the work covered by the application could not be defined as a "medical purpose" as required by the Health and Social Care Act, it was unable to approve the request for Section 60 support.

10.35 However, the Advisory Group did agree the information required by the applicant was virtually non-identifiable, and would almost certainly be effectively pseudonymised if the alternative identifiers listed in section (g) of the application were used. It was therefore content for the work to proceed as there would be a very small

chance of any individual being identified given the various safeguards that had already been implemented.

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

9. Any Other Business

Health and Social Care Bill

9.1 The Advisory Group considered a letter from Mr John Hutton, the Minister of State for Health. The letter responded to concerns raised by the Advisory Group in relation to powers proposed in the Health and Social Care Bill to allow the Commission for Health Audit and Improvement (CHAI) and Primary Care Trusts access to patient records.

9.2 Although the Advisory Group remained sceptical that the powers were required, it agreed that its comments had been taken into account and that it appeared that safeguards would be established to ensure that patient identifiable information would be processed only when obtaining consent or using anonymised data was impracticable.

9.3 However, the Advisory Group remained uneasy about the prospect of PCT staff being able to review the records of patients who lived in the same locality and was concerned that the Minister's letter did not address this issue. It was therefore agreed that the Chair should seek reassurance on this issue.

ACTION: Chair to write to Mr Hutton seeking reassurance on PCT access to patient records.

PIAG Principles

9.4 The following issues had been identified as principles during the meeting:

- Applications must address issue of patient involvement and/or consultation with patients or representative groups
- PIAG and S60 only covers England & Wales – patient identifiable information obtained from sources in Northern Ireland and Scotland would not be supported and exempt from the common law duty of confidence
- There should be a culture of offering patients choice by seeking consent – not using S60 to get out of consent issues. Should seek to support patient opt-out rather than avoid because it requires some additional work
- Gaining consent need not be difficult, though there may be times where clinicians need to communicate with patients with greater sensitivity - seek earlier or more generally (e.g. before diagnosed with cancer)
- All applicants should have a policy for archiving and destruction of data, including different data storage formats

- Applicants should 'blur' data wherever possible rather than seeking most accurate 'just in case' (e.g. age rather than date of birth, month or year of birth rather than precise date, postal region rather than full postcode)
- PIAG expects to see information being given to patients about activities and how they can raise concerns
- Data Protection principle of not retaining data unduly, and seeking information 'just-in-case'
- Organisations processing patient identifiable information should have a Caldicott Guardian or equivalent (and appropriately senior with medical training)
- PIAG expects detailed responses to questions concerning DPA and Caldicott Principles - generally expects all questions to be addressed, and applicants to have read guidance documents

10. Date of Next Meeting

10.1 The next meeting of the Advisory Group was scheduled to take place on Tuesday 9 December 2003