PIAG
2-02/2002

PATIENT INFORMATION ADVISORY GROUP

Meeting on Friday 8 March 2002

MINUTES

1. Present

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

In attendance: Dr Grant Kelly, Professor Martin Severs, Mr Graham Pogson, Mr Phil Walker, Mr Alistair Donaldson, Mrs Bev Botting, Mr Sean Kirwan

2. Apologies

Apologies were received from: Sir Cyril Chantler, Dr Patrick Coyle, Ms Julia Palca, Mrs Shahwar Sadeque and Dr Michael Wilks.

3. Minutes of last meeting

3.1 The minutes of the previous meeting that took place on 10 December 2001 (PIAG 1-02/2002) were approved.

3.2 Members agreed that in future draft minutes could be circulated to them for comment and then, following revision, signed off by the Chair in advance of the next scheduled meeting. In this way they could be made publicly available more quickly.

4. Matters arising not covered elsewhere on the agenda

4.1 Action from the previous meeting was reported as follows:

4.2 Minutes 4.11 and 5.9: it was reported that Members' comments had been incorporated into the draft advice to Secretary of State. The revised draft would be considered later on the agenda.

4.3 Minute 4.14: it was reported that the Secretariat had obtained the addresses of disease and other registries and would contact them with

details of how to apply for Section 60 support after an approvals process had been agreed.

4.4 Minute 4.22: it was reported that the Secretariat sent feedback to the HSE on 20 December. Mrs Botting reported that the HSE had subsequently indicated that it would be able to carry out its work under the class support arrangements.

5. Progress since last meeting

(i) PIAG advice to Secretary of State for Health on proposed regulations

5.1 Members considered the a paper which set out the Advisory Group's advice to the Secretary of State on proposed regulations to be laid under Section 60 of the Health and Social Care Act 2001 [PIAG 1-04(a)/2002].

5.2 Mr Walker reported that the advice had been well received by Ministers who had agreed with recommendations made by the Advisory Group.

5.3 Professor Haines expressed concern about the status of the HSE's application for Section 60 support, as he felt it was important that the Advisory Group did not close the door to a revised application.

5.4 Mrs Botting reported that the HSE had indicated that it would be able to carry out its work under the class support arrangements.

(ii) Summary of responses to consultation exercise on Section 60 regulations

5.5 Members considered a paper that summarised the responses to the consultation exercise on Section 60 regulations [PIAG 1-04(b)/2002]. It was reported that the consultation exercise had ended on 31 January.

5.6 Mr Hake commented that the regulations only covered activities in England and Wales, and asked about arrangements for activities that included Scotland. Mr Walker replied that devolution meant that Scotland was covered by a separate legal system, and a decision had been taken not to legislate in this area. He acknowledged that as a result problems might arise in the future.

5.7 Ms Miller noted that a relatively small number of patient organisations had responded to the consultation exercise, and that those that had all appeared to be opposed to Section 60. Mr Kirwan advised members that the consultation documents had been sent to a range of nationally recognised patient organisations, and Ms Meredith added that the Patients Forum had forwarded the documents to about 60 affiliated patient groups. The Advisory Group recognised that some patient organisations had insufficient resources to enable them to participate in

activities such as the consultation exercise, and agreed that additional efforts would have to be made in the future in order to ensure that patients' views were not overlooked.

5.8 Ms Miller also queried whether research ethics committees had been invited to participate in the consultation exercise. Mrs Botting replied that she had discussed Section 60 with Professor Terry Stacey, Director of the National Office of Research Ethics Committees, and had been advised that RECs were mainly concerned to have their own role within the Section 60 arrangements clarified.

5.9 Sir Denis Pereira Gray asked whether the Department had commissioned work to test the assertion made by several respondents to the consultation that the proposed regulations breached the provisions of the Human Rights Act. Mr Walker replied that government solicitors had confirmed that the proposals were compatible with the HRA.

5.10 Professor Haines asked what had been done to address concerns about the use of genetic information that had been raised by a number of respondents. Mr Walker replied that the Human Genetics Commission had been invited to address a future meeting of the Advisory Group so that these issues could be discussed in more detail.

5.11 Professor Haines also asked if the Medicines Control Agency had indicated whether or not it was likely to apply for specific regulations to support its activities. Mr Walker replied that he had discussed Section 60 with MCA officials and they did not think that they required specific support at the current time.

5.12 Dr Cresswell said organisations needed to be reminded that Section 60 was not the sole means of obtaining patient identifiable information – other statutory provisions were in place. Professor Higgins added that there was also a need to emphasise that Section 60 was a transitional arrangement.

(iii) Revised regulations

5.13 Members considered a copy of the revised draft regulations to be laid before Parliament under Section 60 [PIAG 1-04(c)/2002].

5.14 Ms Meredith expressed concern that Regulations 2(1)(b) and 2(1)(c) included reference to "social care". Her concerns were linked to the fact that the NHS and Social Services worked under different statutory frameworks, and that many patients would be concerned if they thought it was possible that their personal information could be share with Social Service departments.

5.15 Although it was noted that the regulations would not permit Cancer Registries to disclose patient information to third parties, including Social Service departments, it was agreed that it would be appropriate

to ask the Department of Health's solicitors if it would be possible for the regulations to be changed so that confusion on this point could be reduced.

5.16 Mr Hake advised the group that "social care" and "social services" should not be regarded as inter-changeable terms – social services provided just one element of social care. His suggestion that the term "health related" should be used in place of "social care" in the regulations was agreed.

5.17 Professor Severs expressed concern that the registration process described in the regulations, detailing activities which had received PIAG approval, might also be regarded by some organisations as approval for the information standards, including data-set structures, they intended to adopt. He wished to ensure that such organisations were aware of the role of the Information Standards Board.

5.18 The Advisory Group recognised there was a need to clarify the interface between PIAG and the ISB in this area. It was agreed that Mr Walker and Professor Severs should agree next steps.

ACTION: Mr Walker and Professor Severs undertake work to clarify the interface between the PIAG and ISB approvals processes.

6. Approvals Process for Class Support

6.1 Members considered proposals for approving applications to carry out activities covered by the class support arrangements [PIAG 1-05/2002].

6.2 It was noted that members had requested at the previous meeting a paper describing the criteria that would allow patients, the wider public, and organisations that believe they require Section 60 support to see on what basis it would be possible to use patient identifiable data without consent. The paper set out proposals for an approvals process to be considered and, if approved, overseen by the Advisory Group. The paper also described arrangements for establishing a publicly available register of all approved activities.

6.3 Members felt that section 3 of the paper needed to be strengthened in order to emphasise that organisations would be expected to be more proactive in the steps they took to reduce their use of patient identifiable data without consent. For example, it was suggested that as part of the applications process for Section 60 support organisations should be required to demonstrate what attempts they had made to obtain consent from patients to use their data and to explain why these efforts had failed.

6.4 Members agreed that there should be a mechanism that would allow organisations to re-submit applications that had not been approved by the Advisory Group.

6.5 The Advisory Group also agreed with Mr Hake's proposal that the applications process should seek more information about organisations' plans to destroy databases that held patient identifiable data.

6.6 It was also agreed that the register of activities supported by Section 60 should provide information about the sorts of information organisations held about patients. This meant that applicants would have to list each of the data-fields they proposed to include in their data-set.

6.7 With regard to the approvals process, the Advisory Group agreed the following:

- Clinical audit carried out within organisations should not require approval or be required to register centrally.
- Organisations seeking support for research studies where there was a financial incentive for clinicians to recruit patients should be required to provide additional information in order to ensure that the use of patient identifiable information could be justified as being in the interests of patients and the wider public.
- Consideration should be given to establishing an inspections process in order to identify organisations which were operating beyond the limits set by the Advisory Group when applications were approved.

6.8 Dr Cresswell recommended that guidance should be issued to organisations clarifying which routine activities could continue without requiring Section 60 support as they were already supported by other legislation (eg notification of some infectious diseases, etc).

6.9 In addition, Dr Cresswell questioned whether the Advisory Group should consider the status of large centrally held databases that held patient identifiable information, such as the NHS-Wide Clearing Service, the Health Episodes Statistics system, and the primary care "Open Exeter" system. Ms Meredith added that patient organisations would welcome a cautionary approach to the use of Section 60 powers and would therefore support PIAG considering whether the NWCS, HES and similar databases required Section 60 support.

6.10 It was agreed that those responsible for maintaining these national databases should be asked to present evidence to PIAG in respect of:

- The current basis in law for data to be processed
- The need for Section 60 support

- Plans to either rely on consent or pseudonymised data in the future.

ACTION: Mr Walker to invite responses from NWCS, HES and others.

6.11 Mr Walker reported that the Department of Health was developing a process called information governance which would establish the standards that apply to all aspects of information processing within legal and policy requirements. It was intended that integrating these within a unified framework would serve as the vehicle for meaningful performance assessment, year on year improvement and gradual cultural change within the NHS. He proposed that the approvals and annual review processes for Section 60 support should be linked to the monitoring and performance management arrangements being developed under information governance, and agreed to report back to the next meeting on how this would work.

ACTION: Mr Walker to report back to Advisory Group on development of monitoring and performance management arrangements under information governance.

7. Applications for Section 60 Support

(i) Application submitted by Professor M Langman to support research project entitled, "Sudden death in the Community: an examination of drug exposure as an antecedent factor"

7.1 The Advisory Group considered an application from Professor Michael Langman (PIAG 1-06(a)/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.

7.2 Members felt that the application did not contain enough information to justify granting Section 60 support. Members expressed the following concerns:

- The application did not explain why the information it required could not be obtained from the General Practice Research Database held by the MCA;
- The applicant had not provided evidence of information it had produced to advise patients about the research study (eg leaflets and posters to be made available in GP practices). The provision of such materials was important as patients should, wherever possible, be allowed to opt-out from having their information used for research studies.
- The applicant had not satisfactorily completed section (x) of the application form. More information was needed about when data would be destroyed.

- The applicant should state whether any individuals or organisations had financial incentives linked to the number of patients for which they provided information.
- The applicant had not provided a strong explanation for why it would be impracticable to obtain patient consent. Members did not feel that Section 60 should support activities where consent would not be sought because it might be denied, and did not believe that it was legitimate to claim that obtaining consent would unnecessarily delay the study when it had already been delayed for almost 2 years.

7.3 Members agreed that the Secretariat should provide the applicant with feedback and seek a revised application. It was agreed that a revised application could, if necessary, be considered by a panel of 3 Advisory Group members (at least one of which should be a lay person) to speed up the approvals process for the applicant.

ACTION: Secretariat to:

(i) provide applicant with feedback and obtain revised application

(ii) to establish a panel to consider the revised application.

(ii) Application to cover the activities of the UK Renal Registry (Adult & Paediatric)

7.4 The Advisory Group considered an application from the UK Renal Registry (PIAG 1-06(b)/2002). The application sought Section 60 support to collect patient identifiable information to be used for the following purposes:

- Supply details of demographics, treatment numbers and changes, treatment quality and outcomes.
- Data comparisons with national standards for benchmarking and quality assurance.
- The assessment of contract activity and service delivery.
- Improve equity of access, adequacy of facilities, availability of important therapies and use of resources.

7.5 Members did not feel they could approve the application on the basis of the information provided. Particular concerns were as follows:

- The application did not adequately address issues around obtaining consent. Members believed that since renal diseases are long-term conditions, with clinicians having regular contact with patients, more could be done to obtain consent to use patient identifiable information – even if this was not at the point of diagnosis.
- Although the application cited the failure of a large scale renal registry in Europe to maintain contact with patients it

did not describe the reasons for failure or whether any lessons had been learned.

- The application described electronic transfers of data. Clarification was needed as to whether data was encrypted.
- The applicant had not provided details of an NHS sponsor.
- The applicant had not provided details of an individual responsible for data security within the Registry.
- The applicant had not provided details of how long data would be retained and how it would be destroyed.
- Professor Severs was concerned that the Information Standards Board had not approved the creation of a national renal data-set and given that the data-set had no DH sponsor and it did not occur in the data manual it could not be regarded as an established standard.

7.6 The Advisory Group agreed that the Secretariat should provide feedback to the UK Renal Registry and invite it to submit a revised application.

ACTION: Secretariat to provide feedback to UK Renal Registry and seek revised application.

7.7 It was also agreed that Professor Severs and Mr Walker should discuss the need for guidance to cover applications for Section 60 support for national data-sets where the ISB needed to consider whether the proposals met information standards.

ACTION: Professor Severs and Mr Walker to discuss PIAG/ISB interface and need for guidance.

8. Miscellaneous Information

8.1 Members received the following documents for information:

(i) Department of Health Confidentiality Strategy (PIAG 1-07(a)/2002), "Building the Information Core", which described the different strands of work that the Department was carrying out to meet legal, ethical and policy requirements on patient confidentiality, and set out the timetable for achieving them.

(ii) Briefing Note on Pseudonymisation/Anonymisation (PIAG 1-07(b)/2002) which was distributed to members because it included information about the problems of using the NHS number for record linkage.

(iii) WMA statement on ethical considerations regarding health databases (PIAG 1-07(c)/2002).

9. Future Meetings of the Advisory Group

9.1 Members noted that the next meeting of the Advisory Group had been arranged for 20 June 2002.