# PATIENT INFORMATION ADVISORY GROUP

## Meeting on Monday 10 December 2001

## MINUTES

### 1. Present

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

In attendance: Dr Patrick Coyle, Dr Grant Kelly, Dr Barry Evans, Mr Graham Pogson, Mr Phil Walker, Mrs Bev Botting, Mr Sean Kirwan

### 2. Apologies

Apologies were received from: Ms Helen Miller, Professor Sir Denis Pereira Gray, Mrs Shahwar Sadeque and Professor Martin Severs.

### 3. Patient Information Advisory Group

(i) Terms of Reference

3.1 Members considered the draft terms of reference for the Patient Information Advisory Group as set out in paper PIAG 02(a)/2001. It was agreed that the terms of reference for the Advisory Group were to:

- *Advise the Secretary of State on use of powers provided by section 60 of the Health and Social Care Act 2001, and in particular on:*
  - *Applications and proposals for use of these powers;*
  - *Draft regulations made under s60(1) of the Act;*
  - *Proposals to vary or revoke such regulations following the Secretary of State's required annual review of existing provisions.*

- *Advise the Secretary of State on key issues, particularly those of national significance, relating to the processing of patient information.*

(ii) Update on Section 60 of the Health and Social Care Act 2002

3.2 Members considered a background paper (PIAG 02(b)/2001) which described the background to Section 60 of the Health and Social Care Act 2001 and the establishment of the PIAG.

3.3 In addition, Mr Walker stressed that Section 60 was a transitional measure – it existed solely to give essential NHS activity which relied upon patient identifiable information a legal basis to continue until the NHS had set in place a practicable means of obtaining informed consent from patients or developed an effective mechanism for anonymising or pseudonymising data. This was emphasised by the fact that each use of the powers created under Section 60 would need to be reviewed annually.

3.4 Ms Meredith said that the PIAG would need to take extra care when considering regulations to cover sharing patient data with organisations involved in the delivery of social care because they worked under a different statutory framework to that of the NHS. Dr Coyle agreed that this was an important consideration and told the group that the Security & Confidentiality Advisory Group had already considered requests from local authorities for access to NHS information.

3.5 Professor Haines said that there was a need for the Advisory Group to input into the Department of Health's communication strategy so that it could engage the public in a debate about how their information was used. Dr Wilks agreed and said that the Group also needed to be party to the Department's work on achieving informed consent.

## 4. Applications for Section 60 support

4.1 Mr Walker reported that officials from the Department of Health had consulted with a range of organisations on the practicalities of how Section 60 should operate. The consensus had been that there should be class support for a broad range of activities which were relatively common-place within the NHS, and an applications process to cover other specific activities.

4.2 He advised the Group that the application form had been structured to find out why organisations needed Section 60 support and why they could not obtain informed consent.

4.3 The applications which were to be discussed by the Group were also subject to a public consultation exercise which was due to run until the end of January 2002. Members were advised that consultees had been asked to consider, but not to restrict themselves to, the following questions:

- *Should there be a publicly available register of approved research and other activity supported under section 60?*
- *Should there be a requirement for data handling standards – that for identifiable information, the name and address should*

*be held separately (with a linking key) from the clinical part of the record?*

- *What limits need to apply and what safeguards are necessary to protect patient interests?*

(i) Application for Section 60 Support from the United Kingdom Association of Cancer Registries

4.4 The Advisory Group considered an application for Section 60 support from the United Kingdom Association of Cancer Registries (PIAG 03(a)/2001) which had been submitted on behalf of a number of different registries which all served a common purpose. The application sought support for obtaining patient information for use on cancer registry database, and it described the main functions of Cancer Registries as:

- monitoring trends in cancer incidence;
- evaluating the effectiveness of cancer prevention and screening programmes;
- evaluating the quality and outcomes of cancer care;
- evaluating the impact of environmental and social factors on cancer risk;
- supporting investigations into the causes of cancer;
- providing information in support of cancer counselling services for individuals and families at higher risk of developing cancer.

4.5 It was reported that much of the Department's consultative work had highlighted the need for Section 60 support for Cancer Registries. The application was supported by Professor Mike Richards, the National Cancer Director, as Cancer Registries were regarded as having a key role underpinning the National Cancer Plan.

4.6 With respect to obtaining informed consent from patients, Dr Wilks was concerned that the application suggested that informing patients about their cancer registration was too burdensome for doctors. He said that the Advisory Group should bear in mind the amount of contact between clinicians and patients, and that consent needn't be at the point of diagnosis. However, Dr Cresswell advised members that cancer registries needed to receive information about patients from a wide range of sources that did not have close contact with patients. It was recognised, however, that much could be done to make patients more aware of the work of registries, and that NHS organisations had a duty under the fair processing requirements of the Data Protection Act 1998 to inform patients about how their information was used including that it may be passed to organisations such as registries.

4.7 In relation to data handling, Dr Coyle was concerned that the application indicated that cancer registries might pass patient information to third parties. He said that it was important to ensure that other organisations had the same security and data handling standards as the applicants. It was agreed that disclosures of patient identifiable information by cancer registries to third parties should not be supported by inclusion in the regulations covering the activities of

cancer registries but that such disclosures should be supported by appropriate consent, anonymisation procedures or specific Section 60 regulations.

4.8 The Advisory Group expressed concern that there were apparent problems in using the NHS number for record linkage with other organisations. Mr Hake reported that Social Care organisations experienced difficulties in obtaining the NHS number, and members noted that cancer registries often had to link their records with those of organisations that did not have access to the NHS number. Mr Walker was asked to provide a note to the Advisory Group describing issues around using the NHS number for record linkage.

**Action: Mr Walker to report back to the PIAG on issues around using the NHS number for record linkage.**

4.9 Mr Hake questioned the need for cancer registries to retain patient information indefinitely as set out in the application. The Advisory Group agreed that registries should be asked to justify the retention of data they held, and to publish retention and disposal policies.

4.10 Sir Cyril Chantler noted that the application made no reference to the need for cancer registries to develop mechanisms for obtaining consent from patients to use their information or to establishing methods for using anonymised data. The Advisory Group agreed that the registries should be required to set out their plans to devise procedures which would allow them to use patient identifiable information without recourse to the interim powers available under Section 60.

4.11 The Advisory Group concluded its discussions in relation to the application from the UKACR by agreeing that the activities of cancer registries should receive section 60 support, subject to the caveats described in paragraphs 4.6 – 4.10 above. In addition, it was agreed that members should send written comments about the application to the Secretariat.

**Action: Members to forward any additional comments on the UKACR application for s60 support to the Secretariat.**

(iii) <u>Generic Application for Section 60 support to cover Disease and other registries</u>

4.12 The Advisory Group considered a "generic" application to cover disease and other registries (PIAG 03(b)/2001). Mr Walker reported that this had been prepared by Dr John Newton who had been commissioned by the Department of Health to identify the common characteristics and requirements

4.13 However, the Advisory Group agreed that the generic application was an inappropriate means of providing Section 60 support to the activities of disease and other registries. Members felt that individual registries should be encouraged to submit their own applications. It was suggested that the Secretariat should attempt to arrange

applications thematically so that it would be easier to identify areas of commonality for class support. Ongoing work by the Secretariat will help define the criteria for class support including standards for disease registries. It was agreed that the Advisory Group would consider this at its next meeting.

4.14 In the interim, the Advisory Group agreed that the Secretariat should write to all disease and other registries to alert them to the process for applying for Section 60 support.

**Action: Secretariat to write to disease and other registries with information about the application process for Section 60 support.**

(iv) Application for Section 60 support from the Public Health Laboratory Service

4.15 The Advisory Group considered an application for Section 60 support from the Public Health Laboratory Service for obtaining patient information for communicable disease surveillance and control. The application covered infections such as heliobacter, E.coli and vCJD that are not covered by statutory requirements for notification, and it was proposed that information would be used to:

- Recognise, control and prevent communicable disease;
- Provide support for improving the provision of patient care and treatment;
- Informing patients about their diagnosis and exposure to communicable disease.

4.16 Dr Evans, of the Communicable Disease Surveillance Centre, was attending the meeting to discuss the application in more detail. He highlighted a number of issues:

- The PHLS took the recommendations of the Caldicott Report very seriously and was moving towards fully achieving its requirements;
- It was keen to limit the use of patient identifiable information and was employing pseudonymisation techniques wherever possible. 85% of its records did not contain patient names, and the PHLS was moving towards a similar figure for full postcode;
- The PHLS has a policy of removing and permanently destroying patient identifiable information after 2 to 5 years from records that contain such information at the time of reporting;
- The PHLS was trying to communicate more effectively with patients and professionals about the reasons it required patient identifiable information, by producing posters and leaflets;
- It was exploring options for allowing patients to opt-out of having their information used;
- It was important to recognise that the PHLS undertakes 12 million investigations on clinical specimens each year most of which proved negative – it was therefore very difficult to obtain informed consent for this amount of activity;

- The PHLS was keen to act quickly to prevent the spread of communicable disease – in some cases the wider public interest must take precedence.

4.17 Professor Higgins reported that she had received concerns from Mrs Sadeque about the PHLS application. In particular, she had found the section on Patient Consent (p37 of the application) unacceptable. Mrs Sadeque had served as a member of the MRC Working Group to develop operational and ethical guidelines on tissue collections which recommended that informed consent should always be obtained from patients; she was therefore concerned that the PHLS had stated that it was not able to meet these requirements and was therefore unwilling to support its application.

4.18 In response to these concerns, Dr Evans explained that GPs were often unaware of the way the PHLS operated and would therefore have difficulty explaining its work to patients. In addition, providing patients with a full explanation of the PHLS and its work, and answering any questions that patients may have, would be a burdensome task for GPs. However, Ms Meredith stated that the PHLS would need to demonstrate that it intended to address these concerns and demonstrate how it was going to move forward to assure patients that their information was not being shared unnecessarily without full discussion.

4.19 Professor Higgins thanked Dr Evans for his contribution to the meeting, and also commented that the PHLS had submitted a strong application which addressed many of the issues which were of concern to the Advisory Group. Members agreed to support the PHLS's application.

(v) Application from the Health & Safety Executive

4.20 The Advisory Group considered a draft application for Section 60 support from the Health & Safety (PIAG 03(d)/2001) to obtain patient information for research into long-term risks associated with occupation.

4.21 Members agreed that the HSE's application did not include enough information about its activities and the specific reasons for which it required Section 60 support. Dr Cresswell said that the HSE had not explained to which organisations it needed to link its records. Dr Kelly suggested that the HSE should provide worked examples of studies it had undertaken so that the Advisory Group could have a better understanding of the reasons for its application.

4.22 The Advisory Group agreed that it could not support the HSE's application in its current form. The Secretariat should provide advice to the HSE about the reasons for this decision and invite it to re-submit after it had taken account of members' concerns.

**Action: Secretariat to communicate the Advisory Group's advice to the HSE and invite it to re-submit its application.**

(vi) Class Support

4.23 The Advisory Group considered a paper (PIAG 03(e)/2001) which set out the case for providing class support for certain activities that were, in many cases, commonplace within the NHS.

4.24 Members of the Advisory Group were supportive of the need for class support for certain activities. However, they were concerned that additional safeguards may be required to prevent the arrangements from being misused.

4.25 Dr Catchpole said that the Department of Health should devise criteria which organisations could use to help them decide whether it is appropriate for them to obtain patient information under the class support arrangements. Organisations should also be required to demonstrate the benefits to patients and the wider public of the activities they are undertaking with class support.

4.26 Dr Kelly added that when MRECs/LRECs approve such activities, they should be required to set out why they accepted that it was impracticable to obtain informed consent.

4.27 In response, Mr Walker advised members that Section 60 regulations would support the establishment of a register on to which all activities supported by Section 60 powers would be recorded and that regulations would require those receiving such support to be open to investigation and monitoring.

## 5. Draft Regulations for consultation

5.1 The Advisory Group considered a draft statutory instrument setting out proposed regulations for Section 60 of the Health and Social Care Act 2001 (PIAG 04/2001). Members were advised that the regulations would be laid before Parliament and, if agreed by both Houses, would describe the activities which had a basis in law to use patient information without consent.

5.2 Section 2 of the draft regulations covered activities set out in the application from the UK Association of Cancer Registries and the generic application to cover disease and other registries. Following the Advisory Group's discussion of these applications, it was agreed to recommend to the Secretary of State for Health that this section of the regulations should be confined to supporting the activities of cancer registries.

5.3 Section 3 covered the activities outlined in the application from the PHLS. The Advisory Group agreed to recommend to Secretary of State that these regulations did not required substantial amendment.

5.4 Section 4 covered the HSE's application. The Advisory Group agreed to advise Secretary of State that these regulations should not be supported.

5.5 The Schedule covered class support. The Advisory Group agreed to advise Secretary of State that the Schedule did not require substantial amendment.

5.6 In addition, the Advisory Group recommended that:

- Section 5(2) of the regulations should be revised so that it described in more detail the process for approving activities which required Section 60 support;
- Section 6(1) should require the establishment of a register which recorded all activities which had been carried out with Section 60 support;
- Section 3(2) should not include a reference to the Food Standards Agency;
- The regulations should set out the timescales for reporting activities which have been carried out with Section 60 support;
- The regulations should be more specific about the activities eligible for class support.

5.7 Professor Sir Cyril Chantler suggested that there were four issues which should form the basis of the criteria for approving activities which required Section 60 support:

- Could the applicant demonstrate that it was not practicable to obtain consent?
- Did the applicant require 100% coverage of the relevant patient group?
- Would patients be informed that their details were included on a register/database?
- Had the applicant demonstrated that they had established appropriate data handling standards?

5.8 Members agreed that this was an appropriate starting point for the development of criteria. It was agreed that Mr Walker would produce a paper with revised criteria for consideration at the next meeting.

**Action: Mr Walker to produce revised criteria against which applications for s60 support would be considered.**

5.9 The Secretariat was asked to draft advice to the Secretary of State setting out the Advisory Group's views on the applications for Section 60 support and the draft regulations, subject to additional written comments from members. It was agreed that members should be allowed to comment upon the draft advice before it was submitted to Secretary of State.

**Action: (i) Members to send written comments/amendments to the Secretariat;**

**(ii) Secretariat to draft the Advisory Group's advice to Secretary of State and circulate to members for comment.**

## 6. Future Meetings of the Advisory Group

6.1 Members were asked to communicate their availability for future meetings to the Secretariat. Meetings of the Advisory Group during 2002 were subsequently arranged for the following dates:

- Friday 8 March
- Thursday 20 June
- Monday 9 September
- Thursday 5 December

## 7. Any Other Business

7.1 There was no other business.