PATIENT INFORMATION ADVISORY GROUP

Meeting on Tuesday 7 December 2004

Minutes

1. Present

Members: Professor Joan Higgins (Chair), Professor Michael Catchpole, Dr Tricia Cresswell, Mr Michael Hake, Ms Barbara Meredith, Professor Sir Denis Pereira Gray.

In attendance: Mr Patrick Coyle, Mr Alistair Donaldson, Mr Jim Shannon and Ms Karen Thomson

2. Welcome and apologies

2.1 The Chair welcomed Mr Jim Shannon to the meeting. It was noted that in future he would be the contact with the Department of Health. Mr Shannon informed the Advisory Group that he was the policy lead for confidentiality and reported to Mr Phil Walker. Mr Shannon was responsible for supporting the Health Record and Data Protection Review Group and was also part of the National Care Record Service Confidentiality Requirements Group, within the National Programme for IT, which looked at the detail of 'Legitimate Relationships', 'Role-based access controls' and 'Sealed envelopes'.

2.2 Apologies were received from Ms Julia Palca, Dr Michael Wilks and Professor Martin Severs.

3. Minutes of the last meeting

3.1 The minutes of the previous meeting of the Advisory Group that had taken place on Monday 13 September 2004 [PIAG 3-03/2004] were agreed to be a true record subject to some minor amendments.

4. Matters arising

The Advisory Group considered the Secretariat report and the following items were discussed:

<u>NICE and the Confidential Enquiries</u>

4.1 Ms Thomson reported that the National Institute for Clinical Excellence (NICE) and the Confidential Enquiries had responded to the Advisory Group's request for an update within six months. It was noted that the Confidential Enquiries would come under the auspices of the National Patient Safety Agency (NPSA) from 1 April 2005. The Enquiries have

been in discussion with the National Programme for IT (NPfIT) with respect to how the secondary uses service might address their needs. NICE had reported that the secondary uses service would be unable to deliver the level of detail required by the Enquiries for some considerable time. Additionally Ms Thomson informed the Advisory Group that posters about the work of the Confidential Enquiries were shortly to be distributed for display within hospitals and GP surgeries.

4.2 The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) had provided a very detailed report, including a security risk review undertaken by an external consultancy firm. NCEPOD confirmed that they would be implementing the recommendations from the review within twelve months. The Enquiry indicated the improvements, undertaken or planned for user involvement and new work to make the Enquiry more visible to the community at large. The Enquiry highlighted that there appears to be a difficulty in asking hospitals to calculate age from date of birth as it was sometimes reported incorrectly. The Enquiry was therefore continuing to ask for date of birth but deleting it, once age had been correctly calculated. Similarly where additional identifiable information, such as name, was required to link with data from the ONS, then this information would be retained only until the link had been made and then it would be removed from the NCEPOD dataset.

4.3 The Confidential Enquiry into Maternal and Child Health (CEMACH) reported that they had undertaken a security risk review and were making improvements following this. The Enquiry had no new data streams, but would provide information about the project into childhood deaths, as previously outlined, once the protocol had been agreed. They had also recruited lay representatives to their Board and Advisory Committees, and were piloting the use of lay people as panel assessors. The Enquiry had reported that they had developed an internal protocol for pseudonymisation. In line with this protocol, all their regional offices now have access to NSTS with a view to using the NHS number. Also, identifiers would be held separately or, if required for analysis, would be encrypted. Implementation of the protocol would be phased in over the coming few months.

4.4 The Confidential Inquiry in Suicides and Homicides (CISH) confirmed that their data was held separately from that for the Centre for Suicide Prevention. The Inquiry reported that from December 2004, the NHS number would be available from the ONS, enabling the Inquiry to monitor how robustly the number had been recorded and whether it would be feasible for the Inquiry to use the NHS number in future. The Inquiry would continue to require other identifiers for some time while this was being evaluated. Additionally there would remain an ongoing need for other identifiers for the homicide inquiry to enable linkage with Home Office records. The Inquiry has developed relationships with a range of appropriate patient and carer groups and now has lay representation on the Inquiry's steering group. Additionally the Inquiry submits all its work to COREC before embarking on any new work. The Inquiry raised the issue

of security as they were now operating on two sites. Currently only one site has access to identifiable data but the Inquiry wants to enable data-sharing across the two sites and have asked for the Advisory Group's guidance to ensure the Inquiry satisfies PIAG's data security requirements in making these changes.

4.5 The Advisory Group warmly welcomed the significant progress made by the Confidential Enquiries in the last six months. In light of this and of the imminent move to the NPSA, the advisory group agreed that the Enquiries should next report on their progress in twelve months. This is subject to Mr Donaldson being satisfied with the security arrangements in particular with respect to the changes in the way CISH will operate.

Action: Chair to write to the Enquiries to thank them for their efforts. Secretariat to respond to any outstanding issues to the Enquiries.

Appointments process

4.6 Ms Thomson reported on the appointments process for new members. It was anticipated that there would be new members attending the March meeting. The Chair reported that the recruitment information had highlighted mental health, academic research, cancer, and research ethics committees as areas that the advisory group sought to strengthen relationships with. This was with a view to encouraging applicants from those areas. It was confirmed that re-appointments would be confirmed at around the same time as new appointments.

University of Bristol Application:
Evaluation of population based screening for localised prostate cancer in the UK, case note review [PIAG 3-06(e)2004].

4.7 The Advisory Group considered the information supplied by the University of Bristol in support of this application.

4.8 The key issue was the need to access records of huge numbers of people who did not have cancer and who had not given their consent. It was also clear that consent would need to be sought for screening in due course. However with this particular project seeking consent was almost an intervention in itself, as it may prompt people to seek screening, thus opening the research to contamination. The Advisory Group was extremely concerned about the huge numbers involved and of setting a precedent. Concerns were also expressed about the security arrangements such as the use of portable devices. It was noted that part of this project had already been supported by Section 60. It may also be that research taking place in the USA may answer the research question being addressed by this project, in which case there may be no need to duplicate this work.

4.9 It was agreed that further discussion with the research team should be undertaken by the Secretariat, Dr Cresswell and Professor Catchpole, reporting back to the wider membership. In particular, it was agreed that

the research team should be asked to undertake the user involvement activity outlined in their revised application.

Action: Dr Cresswell, Professor Catchpole and Ms Thomson to discuss further with the applicants.

5. Lord Warner's Ad Hoc Advisory Group in NHS Research Ethics Committees.

5.1 The Chair informed members that she had been asked to make a presentation to Lord Warner's Ad Hoc Advisory Group on PIAG's perspectives on the work of RECs. She proposed to submit a written statement in addition to the presentation. The Chair invited members to contribute their thoughts about what specific messages she should incorporate. The discussion that ensued included the following:

- PIAG oversees activities that are not considered by RECs.
- The question is not how to remove regulatory blocks to research but to consider how regulation can be achieved most efficiently and how research activities can be most effectively defended.
- There is significant misunderstanding in the research community about PIAG's role and the perception that it is a barrier to research rather than supporting activities that otherwise might have no legal basis to continue.
- PIAG has concerns about passing on or delegating some of its authority to RECs both because it has a wider remit and because RECs have not been consistent in their decision-making and PIAG has seen examples of manifestly poor Caldicott compliance and data security, which RECs have passed.
- PIAG has led to improvements in how data is handled within research and NHS bodies and ensured that proper regard is paid to confidentiality and consent e.g. The Confidential Enquiries.
- A joint application form might be a useful method of reducing the administrative task and that RECs could have a role in screening applications to ensure that only those that needed Section 60 support were seen by PIAG.
- The importance of working from the principles of creating a patient-centred NHS, by showing respect for individuals by maintaining confidentiality and seeking consent for uses unrelated to their care.

Action: Chair to draft statement for the Ad hoc advisory group

6. Academy of Medical Sciences Study on the Use of Patient Data in Research

6.1 There was a discussion about whether the Advisory Group should make a long or a short response to this call for evidence. Concern was expressed that the document Strengthening Clinical Research and the proposed study, both appeared to be based on the premise that regulation is an unnecessary barrier to research and that it should be reduced. It was agreed that a

detailed response was appropriate provided it did not lend validity to this premise. There were a number of more specific comments on the draft submission. As the deadline for submissions was imminent, it was agreed that the Secretariat would revise the draft in light of these comments and that Ms Meredith and Ms Thomson would finalise the submission with the Chair before sending it to the Academy.

Action: Chair, Ms Meredith and Ms Thomson to revise and finalise the document before submitting response.

7. Consultation: Access to relevant documents, records and data to counter NHS fraud.

7.1 The Advisory Group considered the consultation document: *Access to relevant documents, records and data to counter NHS fraud*. The Advisory Group recognised that preventing and detecting fraud was in the public interest to ensure that money was not misspent. It was acknowledged, that whilst fraud was generally minor in nature, this was not always the case. Nevertheless, the Advisory Group felt that this consultation document had failed to convey any understanding of the difference between records in general and health records. Health records may contain sensitive information and there is an expectation that it will be treated confidentially and not disclosed outside of the care team without obtaining consent. The prime purpose of the health record is to support clinical care. For this reason, health records cannot be released or removed for investigative purposes but that where necessary a copy should be taken.

7.2 The consultation's comparison with the Department for Work and Pensions did not take adequate account of the differences. With respect to the DWP, the detection of fraud primarily relates to individuals making a false claim. Whilst the remit of the new agency may include looking at patients' fraudulent claims, it is primarily concerned with the business aspect of the NHS. What has been proposed, is access to data where the person under investigation is not the person whose records are being examined.

7.3 The Advisory Group felt strongly that health records could only be examined by a clinically registered practitioner as such records would require interpretation. It was also necessary for access to be limited to someone with a professional duty of confidentiality.

7.4 The consultation document does not look forward to the changes that the National Programme for IT will bring, or how this is likely to impact on counter-fraud investigations. This work should obviate greatly the need for access to identifiable patient records, if not entirely.

7.5 The Advisory Group recognised that in general, consent would be inappropriate, however, the document fails to differentiate between when pseudonymised data might be suitable and when identifiable data would be required.

7.6 There was considerable concern at the lack of protection for patient confidentiality. The consultation document appeared to be asking for 'free to roam' powers. The Advisory Group felt that such powers were unwarranted. It appeared that the fine to be imposed applied only to a failure to disclose information and not also to breaching confidentiality. Additionally, misuse of powers by counter-fraud staff would only be subject to an internal investigation rather than an independent external body. Additionally as the staff will be NHS staff, they should be subject to the same standards as other NHS staff where a breach of confidentiality is an immediate disciplinary offence.

7.7 Serious concern was also expressed about the lack of detail in the document with respect to the new body's security responsibilities. The document was also inaccurate in that responsibility for information security would not lie with the new body.

7.8 It was noted that the police do not have automatic right of access to health records and require a court order. The Advisory Group agreed that the case for access to medical records had not been made within the consultation document and that much work remained to be done. It was hoped that this would be done in consultation with the Advisory Group, in order to find a workable solution.

7.9 It was agreed, following discussion, that the Secretariat would draft a response based on the Advisory Group's comments and circulate it for amendment and approval before the deadline.

Action: Secretariat to draft response and circulate it for approval.

8 Annual Report

8.1 The Advisory Group considered the draft Annual Report. Following discussion it was agreed to produce two annual reports, a longer more substantive document and a shorter more focussed document to communicate PIAG's key messages most effectively. It was agreed that if possible, the shorter document should be designed and printed, with both reports available online. It was also agreed that the publication of the report should have a press release to raise the profile of the Advisory Group and increase public awareness of some of the key issues.

Action: Secretariat to redraft two reports in light of the Advisory Group's comments and circulate for comment and draft press release.

9 Applications

i) British Paediatric Surveillance Unit of RCPCH, HPA, ICH(L) – Epidemiological surveillance of rare childhood disorders and infectious diseases, multiple studies [PIAG 4-08(b)

9.1 The Advisory group considered an application for Section 60 support from the British Paediatric Surveillance Unit (BPSU) for multiple studies into rare childhood disorders. The role of the Surveillance Unit was to facilitate case-finding through a monthly mailing to all paediatricians. The Surveillance Unit did not hold any identifiable data itself but acted as a clearing house, notifying researchers of paediatricians who had informed the BPSU that they had seen a case of a particular condition in the preceding month.

9.2 The BPSU were proposing to act as a delegated authority on behalf of the Advisory Group to consider whether the studies it facilitated required Section 60 support and if so to provide it, reporting to the Advisory Group retrospectively.

9.3 The Advisory Group acknowledged that the work of the BPSU was important and that the studies it supported were required to undergo a rigorous peer review process. Nevertheless, the Advisory Group, neither considered it appropriate nor legitimate to delegate its powers. Members felt that the BPSU would not take the same approach as the Advisory Group in considering applications and would not pay due attention to aspects that the Advisory Group considers important such as data security. Practice was sometimes poor, with the use of stand alone computers, portable devices and with many researchers not based in the NHS. The Advisory Group also felt that using euphemisms such as 'comparator data' for identifiers, was unacceptable.

9.4 The Advisory Group accepted that for studies into rare conditions, very small numbers might mean it was not appropriate to seek consent. In such circumstances, where anonymised information would not suffice, Section 60 support would be required. Where numbers were not extremely small, and this would need to be judged on a case by case basis, seeking consent may be appropriate. Similarly with respect to infectious diseases, whilst speed was sometimes essential, in circumstances where it could take two months for researchers to send questionnaires to consultants, the public interest argument of requiring speed as a justification for not seeking consent, seemed poor.

9.5 It was agreed that there would be benefit in working collaboratively with the BPSU to consider the feasibility of an integrated application form and a prospective process of approval.

Action: Ms Thomson to contact and discuss the above with the BPSU and report progress at the next meeting.

ii) St Thomas' Hospital, London – Study into the relationship between the index of multiple deprivation and the incidence, access to various forms of treatment and outcomes for patients diagnosed with gastric and oesophageal cancer in South East Thames between 1997 and 2003 [PIAG 4-08(c)/2004]

9.6 The Advisory Group considered an application for Section 60 support from St Thomas' Hospital to undertake a geographical analysis of gastric and oesophageal cancer. The Advisory Group felt that, based on the information given, this was a standard geographical analysis and that the work could be undertaken through the cancer registry, without the use of identifiers. It was agreed to refer the applicant to the registry in the first instance. If this was not the case, then the applicant could return to the Advisory Group, with a revised and more detailed application.

Action: Secretariat to notify the applicants of the decision.

iii) Imperial College – Burden of injury in primary care in North West London [PIAG 4-08(d) 2004]

9.7 The Advisory Group considered an application for Section 60 support from Imperial College to undertake a descriptive epidemiological study of injury and short term outcomes. Section 60 support was required because of the use of identifiers and the large number of patients from whom consent would need to be sought.

9.8 The Advisory Group felt that more could be done to pseudonymise the data. It was suggested that a soundex code could be used for linkage in combination with age. Concern was also expressed that if the researchers wanted to undertake a case control study they should begin with consent. Concerns were also expressed about the security risks of using portable devices. The Advisory Group did not therefore feel able to support the application on this basis.

Action: Secretariat to notify the applicants of the decision.

[Note from the Secretariat: Supplementary information from the applicant included confirmation that: identifiers would be held separately from clinical data; the security policy had been developed specifically for this project; full postcode was required to calculate social deprivation scores and for geographical analysis].

iv) Royal Free Hampstead NHS Trust – North-Central and East London Child Health record linkage [PIAG 4-08(e)/2004]

9.9 The Advisory Group considered an application for Section 60 support for a child health register with multiple uses. Section 60 support was required because identifiers were required for record linkage and because consent would not always be appropriate given that one of the uses was to identify children at risk.

9.10 The Advisory Group agreed, following discussion that clarification was needed as to whether this was a pilot for the National Programme for IT with respect to developing the child Electronic Health Record, or whether it was duplicating work that the National Programme would be undertaking. There was also deep concern about the wide range of information that was being gathered and in particular about what would happen to the record once the child reached adulthood, as it appeared that the data would be held indefinitely.
Action: Secretariat to seek clarification from the applicants

v) Mayflower Hospitals – Study into assessing risk in deaf mentally disordered offenders [PIAG 4-08(f)/2004]

9.11 The Advisory Group considered an application for Section 60 support to identify the differences in risk factors for repeat offending, between deaf and hearing mentally disordered offenders. The Advisory Group discussed the communication difficulties involved and concern was expressed about the accuracy of records as a result. It was hoped that qualitative work would be undertaken alongside examining records in order to explore the underlying issues from the perspective of the patients concerned and to test the assumptions about recidivism. It was agreed that accurate actuarial risk assessment was important and commended the hospitals for testing the feasibility of seeking consent. The Advisory Group approved the application subject to satisfactory security arrangements.

Action: Secretariat to notify the applicants of the decision.

vi) University Hospital of Wales, Cardiff – Evaluation of the financial cost, humanistic impact and epidemiology of diabetes. [PIAG 4-08(g)/2004]

9.12 The Advisory Group considered an application for Section 60 support to determine the proportion of secondary care activity and expenditure utilised by people with diabetes. Section 60 support was required because of the use of identifiers for record linkage from multiple sources and longitudinally. Although extensive identifiers would be required it would only be for a very limited time period until record linkage had been established. The Advisory Group approved the application subject to satisfactory security arrangements.
Action: Secretariat to notify the applicants of the decision.

vii) University of Leeds, Unit of Epidemiology and Health Services Research – Retrospective flagging of Barrett's Oesophagus cohort. [PIAG4-08(h)/2004].

9.13 The Advisory Group considered an application for Section 60 support to enable flagging by the ONS to ascertain cancer and death registrations. The Advisory Group were concerned both by the evident lack of understanding of user involvement in the application, and by the use of portable devices in terms of data security. The Advisory Group, however,

approved the application subject to making satisfactory security arrangements.

Action: Secretariat to notify the applicants of the decision.

10 **Diabetic Retinopathy Screening**

PIAG considered a request from the national retinopathy screening programme for clarification about whether Section 60 support was required for the programme as information would need to be shared across several PCTs, hospital clinics and general practices. There had been reluctance on the part of some data controllers to release patient information to the screening programme because of confusion about this. The Advisory Group agreed that call and recall for retinopathy screening was part of the care pathway. As such, consent to sharing relevant data could be implied from information about how patient information is used by the retinopathy screening programme, being provided to patients, and by making it clear patients had the right to opt out. There was therefore no requirement to apply for Section 60 support.

Action: Secretariat to inform the Retinopathy Screening Programme.

11. Arms' Length Bodies to come under Ombudsman's jurisdiction

Ms Thomson reported that she had been contacted by the Cabinet Office, as, following the review of arms' length bodies, it had been mooted that any non-departmental public bodies that interacted with the general public should come under the jurisdiction of one or other Ombudsman, as part of its public accountability. Whilst the Advisory Group does not provide services to the public and does not currently have a high public profile, it may receive enquiries from the public. Following discussion, it was agreed that the Advisory Group should come under the aegis of the Parliamentary Ombudsman.

Action: Secretariat to inform the Cabinet Office

11 Enquiry from the Office of National Statistics

Professor Catchpole raised a question that had arisen in discussions at the Medical Research Advisory Group - whether there was a threshold in terms of size of cohort when it would be unreasonable to expect consent to be sought. The Advisory Group responded that it was a helpful question that clearly needed elucidating further in the Annual Report. The Advisory Group felt that it depended, not only upon size of cohort, but also upon circumstances. Examples might include: how important it was that ascertainment was complete, and the relative difficulty of obtaining consent because of lack of contact with services or the passage of time.

12. Future Meeting Dates

The meeting dates for 2005 will be:

14/15 March
6 June
5 September
5 December