Minutes

PIAG
Patient Information Advisory Group

Meeting held on Tuesday 12 June 2007 at 8.30am

Present:

Members: Professor Joan Higgins (Chair), Professor Mike Catchpole, Dr Tricia Cresswell, Dr Fiona Douglas, Ms Stephanie Ellis, Mr Michael Hake, Ms Ros Levenson, Ms Barbara Meredith, Professor Roy McClelland, Professor Sir Denis Pereira-Gray, Dr Peter Rutherford and Dr Michael Wilks.

In attendance: Miss Anoopa Bharath (Secretariat), Dr Patrick Coyle (SCAG), Ms Melanie Kingston (Secretariat), Mr Sean Kirwan (DHIPU), and Ms Karen Thomson (Secretariat)

Visitors in attendance for the relevant part of the agenda: Mr Jeremy Thorp and Mr Wally Gowing (Secondary Uses Service - Connecting for Health), Mr Christopher Millet, Professor Majeed, Conduit Study, Professor Denise Lievesley (NHS Information Centre for Health and Social Care) and Mr John Sheehan, who would be joining the PIAG Secretariat in July.

1. Welcome and Apologies for absence

1.1 There were no apologies for absence. The Chair welcomed Mr John Sheehan who would be joining the Secretariat in July.

2. Minutes of last meeting

2.1 Minutes of the previous meeting held on Tuesday 6 March 2007 were agreed to be an accurate record, subject to minor amendments.

3. Matters Arising/Action Points

3.1 It was noted that there were still a number of actions outstanding from the last meeting as other priorities had arisen, including the development of draft guidance in relation to the identification of cohorts.

3.2 Child Height and Weight Surveillance Programme

It was noted that a ministerial briefing had been prepared with respect to the further development of the programme for next year. Further comment on the proposed briefing had been submitted to the Department of Health Obesity team, in line with previous comments.

3.3 Outcome of the Awayday – Notes from the Awayday discussions would be prepared and circulated.

Action: Secretariat to draft brief notes on the Awayday discussions for circulation to members

4.2 Information Governance Review

Following the Awayday discussions with Harry Cayton in relation to the Information governance review, members expressed concern that the Care Record Development Board was to be wound up so quickly as although the first pilots had started, there was a need to assess the evaluation of these pilots to ensure that the learning from them was implemented effectively. Members were concerned that this assessment of the evaluation would be handled solely internally.

It was agreed to invite representatives of those involved in the pilots and their evaluation to a future meeting.

Action – Secretariat to invite representatives of those involved in the pilots and their evaluation to the December meeting or another appropriate meeting in relation to the timing of the pilots and evaluation.

4. Secretariat Report

4.1 The Secretariat report was received and its contents noted.

4.2 Appointments

As the Advisory Group had been asked to take on the functions of the Security and Confidential Advisory Group (SCAG), as part of the implementation of the Information Governance Review, members were asked to reconsider how many new members needed to be recruited to accommodate this additional work. The Advisory Group agreed that although it wanted to retain the expertise of members of the SCAG at the same time, members did not want the size of the Advisory Group to become unwieldy. It was agreed that the Chair should determine the size of the membership following further discussions with the Chair of SCAG.

It was agreed that the areas of expertise that should be recruited in terms of new membership should include legal issues, equalities and diversity issues, and the private sector.

4.3. Annual Report

It was noted that the Annual Report for July 2005 to June 2006 had been sent to the printers and would be circulated shortly.

4.4 Approval extensions

It was noted that the following extensions had been approved by Chair's action since March 2007:

HFEA congenital anomalies application [PIAG 1-05(n)/2006]

This required a time extension for an additional six months as the study had had a delayed start.

Breast Cancer screening ICR study [PIAG 3-07(g)/2002]

This was a request for an extension to undertake a data validation exercise with data extracted from Breast Screening Units in place of data extraction from the NHAIS system.

Confidential Enquiry into Maternal And Child Health (CEMACH) [PIAG 4-08(c)/2003]

CEMACH submitted a protocol for a new feasibility study into head injury and requested that their approval be extended to include this new enquiry.

4.5 Information Governance Review - SCAG

It was noted that as part of the Information Governance Review, the Advisory Group had been given the task of taking on the functions of the Security and Confidentiality Advisory Group and that the Chairs of the two Advisory Groups had been charged with implementation. It was noted that this did not require any legislative change as the additional tasks fell within the Advisory Group's second function to provide advice 'on such other matters connected with the processing of patient information or of any information (other than patient information) obtained or generated in the course of provision of the health service as he [Secretary of State] considers appropriate.' [NHS Act 2006 S.252 (3)].

4.6 Options for the future of Payment by Results

It was noted that there was a Department of Health Consultation on Options for the future of Payment by Results, which involved changes to the disclosure of confidential patient information and in particular to the disclosure of identifiable sexual health data. Members commented that the current arrangements with respect to sexual health data are effective in providing additional safeguards to this particularly sensitive information. The purpose in making these changes are financial and the impact of this proposal, to our knowledge has not been assessed. Members regarded this as a major public health issue and this consultation required a robust response. It was noted that the Health Protection Agency (HPA) dataset did not need identifiers and therefore that the driver for this change was purely financial. It was understood that what was being proposed was not even the correct allocation of PCT but allocation of GP practice, which could not be allocated without named information.

The Advisory Group were clear that this information was simply too sensitive, particularly given that some patients may not wish their GP to know they had attended a GUM clinic but this would in effect disclose this information to the GP. It was agreed that this should be excluded from Payment by Results. It was also noted that this should apply to any patient with suspected sexually

transmitted infections both those treated by GUM clinics and in primary care or other community settings.

It was noted that this was likely to be addressed, in due course, by the Secondary Uses Service by the use of the 'Spell' number in place of other identifiers. The Advisory group therefore disagreed with any relaxation of the regulations protecting sexual health data before the system changes have been implemented and robust justification for why identifiable data was necessary.

Action: Secretariat to draft a response to this consultation

4.6 Review of parts of the Public Health (Control of Disease) Act 1984 Consultation

Professor Mike Catchpole declared an interest in this consultation, as he is involved through his work for the Health Protection Agency. In response to concerns raised by members, Professor Catchpole reported that to the best of his knowledge the Department of Health was not minded to propose that cancer registration be included within the proposals, nor to include other conditions where there was not an immediate public health risk. It was noted that the consultation had not addressed the issue of patient identifiable data in any detail but that in general the consultation document presented a balanced and thoughtful approach.

Action: Secretariat to draft a brief response to this consultation

4.7 Commissioning framework for health and well-being consultation

Although the deadline for comments on this consultation had passed, members commented that this document has confused discussion about population level commissioning with individual commissioning and that they need to be separated out as individual level commissioning inevitably involves identifiable data but that population commissioning should not require identifiable data. Members agreed that this comment should be fed back to the consultation team.

Action – Secretariat to feed comments to the consultation team.

4.9 Confidentiality and disclosure of patient information: HIV and STIs consultation

The Secretariat reported that this had been followed up but that the outcome of this consultation had not been made public as yet. It was noted that NHS CFH had additionally held a consultation meeting with sexual health clinicians on 15 March and that the clinicians attending had expressed resounding support for the continuing need for additional safeguards to be in place for sexual health data. In light of the other consultation documents, members agreed that there was a need for further follow up and asked the Secretariat to pursue this

with the Departmental lead for the consultation and Dr Simon Eccles, the NHS CFH Clinical Lead who had been involved in the Conference.

Action – Secretariat to follow up on the outcome of these consultations

4.10 National Patient Safety Agency (NPSA) National Reporting and Learning System (NRLS)

The Advisory Group noted the proposed changes to the National Reporting and Learning System, which would involve disclosure of identifiers. Members felt that the additional cost of pseudonymising the data at a national level and the additional time of two to three weeks out of one hundred days to undertake this work was not excessive. The Advisory Group therefore felt that rather than collecting and using more identifiable data that it would be better if the reporting forms were redesigned to avoid the use of free text. Members felt that part of the difficulty with the NPSA NRLS was that its purpose was unclear and that this was a fundamental issue, as the necessity of identifiable data would then also be clarified. E.g. If wanting to undertake surveillance then there should be a defined dataset with no free text. The Advisory Group noted that a different process would be needed for investigations and that access to identifiable data was more likely to be justifiable for investigations.

It was noted that there were two kinds of reporting with patients being able to report incidents directly and that in such circumstances the information was obtained with consent and therefore could be used with identifiers that had been provided. The Advisory Group recognised that there were important but different issues associated with both.

It was reported that the Medicines and Health products Regulatory Authority (MHRA) have similar problems with respect to the yellow card reporting process and that it was important whether patients had knowledge of whether or not an incident had been reported. Under current arrangements, patients may or may not be aware of whether an incident has been reported.

The Advisory Group agreed that these comments should be fed back to the NPSA, with a view to further discussions taking place as needed.

Action – Secretariat to provide feedback to the NPSA

4.11 Revised Application form

A draft of the revised application was received and was agreed in principle. It was noted that this incorporated questions for extracts from HES in line with the proposal for PIAG to take on the functions of the Security and Confidentiality Advisory Group (SCAG). It was reported that the estimated timescale for building the new integrated study form would begin in late September with a view to the new combined study form being available in December for testing. It was noted that a revised form from non-research applicants was also planned to operate in parallel.

4.12 Identification of cohort issues

The Advisory Group considered an exchange of correspondence between Dr Peter Selby of the UKCRN and Dr Stella Barclay from the Department of Health R & D team with respect to access to confidential patient information in order to identify cohorts of patients in order to seek consent. The Advisory Group broadly agreed with the letter from Dr Barclay in the context of access to confidential patient information for research purposes. The boundary of confidentiality as a general principle lies with the boundary of the clinical care team. The Advisory Group have modified this general principle for local clinical audit following the care pathway where identifiers are needed for record linkage and validation. Although such audit involves access by someone external to the clinical care team and may involve some sharing of information across organisational boundaries, this directly supports the care and treatment of patients through its quality assurance. Such assurance processes are therefore integral to the delivery of care and is a use of patient data that patients might reasonably anticipate. As such, this provides a reasonable basis for implied consent for such local clinical audit purposes. Self-evidently disclosure of identifiers for this purpose should be kept to a minimum and should not be retained longer than is necessary to complete data validation. It should be noted that this does not apply to financial audit, nor to regional or national audits, which should seek to use effectively pseudonymised data. It is envisaged that in due course such local audits will often be able to utilise pseudonymised data via the Secondary Uses Service.

4.13 Freedom of Information request

It was noted that a Freedom of Information request had been received for disclosure of an application for Section 60 support. It was noted that the Freedom of Information Act requires disclosure of information other than personal information other than where an exemption applies. The presumption therefore was in favour of disclosure. Members noted that in this instance, the full application form had been disclosed, as the security information included in Section 5 of the form was not sufficiently detailed to pose a risk to the security of the data. It was noted that where disclosure of information presented a risk that the information could be used to access systems illegally that it would generally be reasonable to withhold information about security measures. It was noted, however, that the balance of public interests must be considered on each occasion and therefore that a blanket rule could not be applied.

4.14 UKCRC Regulatory & Governance Advice Network

It was noted that the Advice network was now being rolled out nationally and that it had resulted in series of queries to the PIAG Secretariat. The responses to the queries would in time be developed into a series of standard responses and Frequently Asked Questions. This was useful additionally, as it would provide information about legal requirements and the Section 60 mechanism to researchers and research governance staff who perhaps may have little knowledge of the Advisory Group. Members commented on what a good outcome this was for the collaboration with UKCRC and proposed that this should be included in next Annual Report.

Action – Secretariat to include details of the collaboration with the UKCRC Regulatory and Governance Advice Network in the next Annual Report.

5. Chair's Report

5.1 Meeting with CTSU, Oxford

The Chair reported that there had been a meeting a meeting with Clinical Trials Support Unit in Oxford on 18 April, to discuss issues in relation to the identification of cohorts and to consider the feasibility of a long-term exit strategy from needing S60 support. The Chair reported that it was a very positive and constructive meeting and provided assurance that for the kinds of studies generally undertaken by the CTSU, another approach was not feasible, at least for the near future.

The Chair also highlighted that having a small group discussion with applicants was a good model for addressing issues. The Chair proposed that a similar meeting should be held with the NatCanSAT team at Clatterbridge. This was agreed by the Advisory Group.

5.2 Dr Foster Intelligence

The Chair also declared an interest in relation to Dr Foster Intelligence (DFI), which had submitted an application to this meeting, as she had been invited to present to the DFI Ethics Committee and as part of the event, had been given dinner afterwards.

6. Applications previously considered

6.1 National Patient Choice Survey PIAG 1-05(d)/2007

This application was considered at the meeting in March 2007. The Application was referred because the Advisory Group had concerns that the approach would not improve response rates from minority communities as intended and therefore this raised doubts about the benefit of disclosure. The Advisory Group had sought additional clarification on a number of aspects, including:

- Security aspects, in particular those related to the transfer of data
- How this proposed method would improve coverage
- The proposed exit strategy from Section 60
- What user involvement (specific to this survey) had been undertaken
- Whether the letter to patients would be on Ipsos MORI or Trust letter headed paper
- Whether hospitals will review the data extract prior to disclosure to ensure non-disclosure of stop noted patients or where there are other sensitivities, which would mean it was inappropriate to contact particular patients.

The Advisory Group considered a response from the applicant addressing these queries. It was apparent that the question relating to developing an exit strategy had not been understood. The Advisory Group also considered this alongside the new application for the GP Patient Experience Survey but differentiated between these applications. For this survey, patients would be receiving communications from the hospital in any case at this time and therefore correspondence related to their appointment would be expected and therefore issues about inadvertent disclosures to family members would not arise.

Following consideration of the further information provided. The Advisory Group agreed to approve the application subject to:

- Further clarification about the development of an exit strategy
- The data extract being reviewed by the hospitals prior to disclosure to filter out patients it would be inappropriate to contact
- It being demonstrated in twelve months that there is added value and benefit in continuing with this approach.
- Confirmation in 12 months of what has been demonstrated as a reasonable but minimal time for retention of identifiers.

Action: Secretariat to inform the applicant of the Advisory Group's decision.

6.2 Department for Transport – HES and STATS19 one to one matching project [PIAG 1-05(g)/2007]

This application was referred at the meeting in March 2007, as further clarification was needed regarding whether the Information Centre could undertake the linkage work on behalf of the applicant, and what the patient / public benefit of the study would be, as the Group had concerns as to whether

this application fell within the scope of medical purposes. The Group also noted that user involvement was poor and needed to be strengthened.

The applicant provided additional information in support of their application, addressing the issues raised. Members agreed that the applicant should be put in touch with INVOLVE to strengthen their user involvement activities. It was agreed that there was a need to differentiate between a single retrospective data collection and prospective data collection and whether consent would be feasible for prospective collection.

It was agreed that subject to further clarification of the above that this project could be approved by Chair's action with the following conditions of approval:

- Re-application for ongoing matching, subject to further consideration of whether consent would be feasible
- Ongoing user involvement with patient public groups interested in road safety issues.

Action: Secretariat to inform the applicant of the Advisory Group's decision

[Note from the Secretariat: Following the meeting, the applicant provided further details about user involvement arrangements and clarified that the application related to a single retrospective data collection and matching and that a revised application would be submitted for future matching once the usefulness of this matching exercise had been established. The application was therefore approved by Chair's action].

6.3 CONDUIT 3 (Cutting out needless deaths using IT) PIAG 1-05(e)/2007

Professor Sir Denis Pereira-Gray declared an interest and withdrew from the discussion of this application as he had attended a lecture of the applicant and had other connections with the Department of Primary Care at Imperial College.

The Advisory Group re-considered this application to allow data extraction from primary care disease registers (within GP practices) and linkage with hospital data for a research study examining the prevalence, incidence and quality of management of diabetes, ischemic heart disease, hypertension, asthma and COPD in primary care in Wandsworth. This application was referred at the meeting in March 2007, as further clarification was needed about a number of aspects. Because of the Advisory Group's concerns, the applicant was invited to attend the meeting to discuss the issues further.

Data collection began in 2001 but it was unclear what had been happening with regard to the use of information and consent since then. The applicant explained that CONDUIT was originally about service development but that more recently a

research component had been added. Originally, there had also not been a need to link data but that now there was a need to link data both across organisational boundaries and longitudinally.

Members felt that the data flows and uses of the data over the period since data had first been collected remained opaque. It was clear, however, that there had been considerable revision of the central purpose of data collection over that period. It was also clear that the data was being used for multiple research studies e.g. VOTES is a longitudinal cohort study.

Members acknowledged the importance of this work and that it was on the border of research and audit as it was likely to have an impact on care provision for patients and whilst supportive of the research, were concerned about the basis on which the project had previously operated.

It was noted that REC approval had been obtained in 2005. The Advisory Group were surprised therefore that Section 60 approval was only now being sought. The Advisory Group agreed that Section 60 approval could not be obtained retrospectively to cover data already disclosed in breach of confidence, for the CONDUIT 3 study. Members suggested that the record linkage should be undertaken in primary care with anonymised data only disclosed outside of the practice or that consent should be sought. Members proposed that the applicant submit an application for CONDUIT 4, taking account of the following comments.

The applicant should address why consent is not feasible prospectively. Given that this group of patients are in regular contact with services, consent should be practicable. If the primary issue is about resources then this should be addressed through funding bids for the research study including adequate resources to seek and obtain consent, taking account of equalities and diversity issues. This is particularly important for this type of research, as research has tended to embed inequalities further. Members recognise this is a broader issue than simply that related to this application but it is particularly pertinent given the disease areas being studied. Testing out the feasibility of seeking consent would provide supporting evidence if the applicant continued to feel that consent was not feasible.

If there are particular sub-groups of the population from whom it is particularly difficult to obtain consent e.g. those frequently not attending for care, or who obtain care outside of the locality, then this should be highlighted in the application.

The Advisory Group also provided comments on the poster for CONDUIT 3. It should be noted that a poster is not sufficient as a mode of informing patients. There must be a leaflet, which is actively disseminated to patients when they come into a practice for clinical review.

The poster did not explain what kind of information would be used, or how identifiable it would be. It was also not apparent where the data would be held and although it had a named contact, did not explain which body was responsible for the

data. If Section 60 were to be used, it should have an opt out mechanism and if undertaken with consent, then explanation that consent may be withdrawn subsequently. The leaflet does not explain what the likely benefit to patient care in general, is likely to be, nor that non-participation will not affect the care and treatment provided to the individual. The leaflet would also benefit from consideration by a Plain English consultant. It should also be available in different languages/media etc.

The Advisory Group felt that as this was a large and established project that investment in good information materials and engagement with local community and patient groups would be enormously beneficial to the quality of the study. Additionally, if undertaken with Section 60 approval, then patient engagement would be a requirement, not replacing consent, but at least ensuring there was patient support for the study and ensuring the study benefited from patient input.

It was noted that the applicant was already exploring the possibility of seeking funding to work with particular population groups.

In conclusion, therefore, the Advisory Group agreed that they could not provide retrospective support for the CONDUIT 3 study and that consent should be sought or data effectively pseudonymised as soon as possible with further linkage undertaken within primary care. It was agreed that the applicant should be advised that an application for CONDUIT 4 could be submitted, if seeking consent for prospective data collection was not feasible.

Action: Secretariat to inform the applicant of the Advisory Group's decision.

7. Fast track applications

Members noted that the following fast track applications had been approved since March 2007.

7.1 Development and validation of risk adjusted outcomes for systems of emergency medical care (DAVROS) [PIAG 2-05(FT1)/2007]

This application from the University of Sheffield was to develop a methodology for evaluation that will focus on developing variables that can act as predictors for survival in the emergency care patient population.

This was approved subject to the following conditions:

- That access is limited to extracting relevant data from hospital systems and notes
- Clarification of how the results from the questionnaire will be linked to pseudonymised data and confirmation of effective pseudonymisation following linkage
- Satisfactory security arrangements

- Confirmation from our security advisor of the 'reversibility' of hash values for date of birth and confirmation of an alternative method if this is not acceptable.

7.2 Pilot study for evaluating the MESH (Managing illness by Empowerment of Self-care and Harmonisation of patient-practitioner agendas) self care support intervention for patients with poorly controlled asthma [PIAG 2-05(FT2)/2007]

This application from Peninsula Medical School, University of Exeter was to develop and refine and nurse training course to enable nurses to deliver the MESH intervention, to establish the feasibility and acceptability (to patients and health professionals) of recruitment, intervention delivery and data collection methods they wish to use in a larger trial and to estimate the likely rates of study recruitment and completion in a larger trial.

No patient identifiable information was to be used in the study. This application was for approval to extract anonymised data from patient notes.

This application was approved subject to the following conditions:

- That a revised application in submitted for the larger study with consideration given to enhanced software solutions that would minimise the number of records to be accessed
- That alternatives are considered with regards to staff undertaking searches under the guidance of a researcher.

7.3 BPSU surveillance study of Idiopathic Intracranial Hypertension (IIH) in children [PIAG BPSU 2-05(FT4)/2007]

This application from the British Paediatric Surveillance Unit was to study the epidemiology of childhood IIH in the UK and Ireland in order to address specific research questions such as:

- The national incidence of various established associations of IIH in children, in particular with obesity at presentation
- The current clinical management of children with IIH
- The spectrum of visual disturbances in children presenting with IIH

This was approved subject to confirmation of satisfactory security arrangements.

7.4 BPSU surveillance study of Congenital Adrenal Hyperplasia (CAH) [PIAG BPSU 2-05(FT4)/2007

This application from the British Paediatric Surveillance Unit was to study the epidemiology of CAH in the UK and Ireland in order to address specific research questions including the following:

- To determine the incidence of clinically presenting CAH children under the age of 16 in the UK
- To report its distribution by age, sex and ethnic group
- To report the clinical features at presentation

This was approved subject to confirmation of satisfactory security arrangements.

8. New applications

8.1 Department of Health – Disclosure and use of NHS commissioning and activity data for the period up to June 2009 [PIAG 2-05(b)/2007]

The Advisory Group considered this application for Section 60 support to allow the disclosure of patient identifiable data from care providers to the Department of Health (DH) (in the form of Secondary Uses Service - SUS) and disclosure from the DH to the NHS commissioning bodies, through allowing the extraction of the Commissioning Datasets (CDS) based data from SUS to proceed.

This is the second application for the Secondary Uses Service and seeks to renew and extend the previous application considered in June 2006 to include new uses, namely data flows to support Payments by Results activities and 18-week referral to treatment times analyses as well as commissioning.

Mr Jeremy Thorp and Mr Wally Gowing were welcomed to the meeting by the Chair and responded to questions from members, some of which have been detailed below. They were not present, however, for the discussion of the application.

The Advisory Group again considered whether or not this should have specific support or if it could be undertaken with class support. The Advisory Group agreed to seek legal advice about this new application as the Advisory Group were concerned not to overstep the boundaries of Section 60. Members recognised that although most of the activities may well fit within the class regulations they were concerned at the breadth of this new application and with the plans to make new applications for other purposes e.g. public health. The question arising from this was whether the use of class regulations remained reasonable as the totality amounted to more than the sum of the parts. Members noted the outcome of the pseudonymisation pilots and were disappointed with the attitude of staff and slowness on the part of NHS bodies to move towards a culture of consent or prepare themselves for using pseudonymised data. Given the recent re-structuring, this was to some degree understandable but remained a source of concern. Members were not convinced that the proposed timetable for switching to using pseudonymised data would be met in light of these difficulties within the NHS and therefore that the applicant would need to re-apply to extend the approval again. It was noted that this was likely to be because of interdependencies with NHS bodies rather than because of delays with NHS CFH, although the issue of how NHS CFH assists the NHS to prepare for using pseudonymised data, remains.

The Advisory Group agreed that there would be benefit for the applicant in regulations being laid before Parliament in order to subject this to the democratic process and enable proper public debate and scrutiny. This would then reduce the likelihood of legal challenge as the Secondary Uses Service would then have a solid legal grounding for obtaining, holding and processing identifiable data in order to produce effectively pseudonymised data extracts but which met the utility requirements for analysis. In particular, members felt that as there was a need for a small central team to have access to identifiable data in order to ensure and verify the data quality in order to provide assurance to users of the validity of the data, that this ongoing need suggested that specific support should be sought.

On the issue of specialist commissioning, members felt that explicit consent could be obtained and that there was an insufficient basis for implied consent. Members proposed that if there were good reasons for an implied consent basis they would wish to see a more detailed rationale.

Members felt that the application had not dealt adequately with the issue of consent particularly in light of the lack of national information campaign for the National Care Records Service. Harry Cayton had confirmed the previous day that information giving was happening locally as pilots for the National Care Record Service were rolled out. Members felt, however, that discussion was often about not overwhelming people by providing too much information. Members felt strongly that the Secondary Uses Service is another package of information to be provided to patients and that there is a need for a national approach as this is fundamentally about the relationship between the NHS and patients. Members felt that the Department of Health /NHS CFH should do more to address this. Mr Thorp agreed that patients being more informed would be beneficial and indicated that the Secondary Uses Working Group, whose report was due to be published shortly, would explain the usefulness of the data.

Members considered whether it was realistic that patients could opt out of data being provided to the Secondary Uses Service. Mr Thorp indicated that anonymised data was sufficient for commissioning purposes and that there were anonymous information flows now but that it required a manual intervention and so could only be done exceptionally at present. The key issue however was that other activities required identifiers e.g. clinical audit, research etc

Members were pleased with the progress made by NHS CFH towards meeting the conditions of approval for the 2006 application. It was noted that following previous discussion about the numbers of users and concerns about registrations and the allocation of User Role Profiles, which determine what a user can do on the system, NHS CFH had conducted a review of user registrations in the Autumn 2006 and reduced the number of users and introduced a more limited set of business functions and tighter registration process.

One of the conditions of approval was that the NHS should not submit data relating to sensitive cases such as sexual health data. Mr Thorp reported that from December last year the Secondary Uses Service had put in place mechanisms to be able to track such cases and remove the data where the NHS had not removed it prior to upload. He indicated that within the system, outpatient and inpatient data was linked together and sometimes it was not possible to tell in advance whether the data would transpire to be sensitive, where this was the case such data was removed.

Members noted that the Security and Confidentiality Advisory Group were monitoring access and that proposals were being developed for the provision of pseudonymised extracts. One of the issues with this was about the risk of disclosure in relation to how far one needed to pseudonymised data in order to avoid the risk of identifiability.

Following discussion, the Advisory Group agreed to seek legal advice about this year's application in relation to the boundary between specific and class support. It was agreed to continue, the previous approval for an interim period of 12 months while the scope of what needs to be presented to Parliament for specific support is considered and then sought. It was agreed that there should be regular updates on progress in the interim. It was agreed that a small group would work with NHS CFH in relation to this. Members who volunteered to participate in the working group were the Chair, Dr Cresswell, Dr Douglas, Ms Ellis and Dr Wilks.

It was re-confirmed that sexual health data, as highly sensitive data should not be included in identifiable form, at the very least until the pseudonymisation process is fully operational and would be re-considered then.

Action: Secretariat to write to the applicants to inform them of the Advisory Group's decision

8.2 Department of Health – National GP Patient Survey 2007/8 [PIAG 2-05(c)/2007]

The Advisory Group considered this application from the Department of Health to conduct the National GP Patient Survey for 2007/2008. The information requested was full name, address, NHS number and practice identifier of the patient.

It was reported that last year, many GPs had declined to participate because of issues about disclosure and that if Section 60 support were to be approved that this may be used to bring pressure to bear on GPs to comply with the proposed process. It was noted that the data to be extracted was not just demographic, administrative data but would include the fact of an appointment with a GP within a specified time frame. Members affirmed their previous view and that of the GMC and BMA Ethics Committee that the fact of a contact with a GP is confidential information and hence that if this activity were to be undertaken using the proposed process that it would require Section 60 approval.

Members further agreed that undertaking the survey as a management exercise was a

legitimate purpose but that this did not obviate the need for Section 60 approval or for an alternative approach to be taken. Members remained to be fully convinced of the need for such detailed sampling given that the survey would be sent to 10% of the population.

It was noted that previously the process as that GPs used to send out the survey and that if this approach were to be used the primary issue is then about ensuring it is done properly. Members wondered why the survey could not be distributed prospectively when patients attended for an appointment.

Members had a number of concerns including whether the questionnaire had been validated. Another issue was that of transparency about the purpose of the survey that it was related to GP pay.

It was noted that there was a fundamental difference between this survey and that of the Patient Choice survey which had been approved, which was that the hospital would be writing to the patient's home in any case and the patient would be expecting this and therefore there was no greater risk involved in the communication about the survey. This was a material difference, as the GP would not be writing out as a matter of course for the GP Patient Experience Survey.

The Advisory Group therefore rejected the application and proposed that the survey be distributed by GP practices directly. Alternatively, the Department could consider other ways of contacting patients such as through use of the electoral roll. Members also wished to correct an inaccuracy in the application form. The exemption under S33 of the DPA was for research and did not apply in this instance, as this was not research but service evaluation. Moreover, it did not obviate the need to comply with the common law duty of confidence, which sits alongside, and is incorporated within, the first Data Protection principle that data can only be processed fairly and lawfully. The disclosure of confidential information therefore would require consent or another statutory basis. The Advisory Group did not consider that there was an over-riding public interest justification for the disclosure, as there were other approaches that could be taken, which would not involve a breach of confidence.

It was agreed that the letter informing the applicant should be copied to Dr Hugh Davies at the National Research Ethics Service.

Action: Secretariat to write to the applicants to inform them of the Advisory Group's decision

8.3 Joint Application for Dr Foster Intelligence and the Dr Foster Unit at Imperial College – Research to identify and publish measures of quality delivery of healthcare by provider, or in some instances by areas and to provide a management information function for the NHS [PIAG 2-05(d)/2007].

The Advisory Group considered two alternative applications with respect to this work. One was a joint application from Dr Foster Intelligence (DFI) and the Dr Foster Unit at Imperial College to replace the previously approved work undertaken by Imperial

College. The rationale for the change was for DFI to take on more of the management functions for the programme of work, freeing Imperial staff to focus on analysis of the data.

The second application was a repeat application for the Dr Foster Unit at Imperial to continue to access identifiable data on the current basis, in the event that the proposed changes were regarded as unacceptable by the Advisory Group.

Members queried the relationship between DFI and the Information Centre. If this work is being undertaken as an agent of the Information Centre then this should be made explicit. It is clear that this project is to some extent at least doing what it is intended, the Secondary Uses Service will provide, with pluripotential uses for the data held by the Imperial College Unit.

Members agreed that the current project was providing an important service to NHS users and therefore agreed to provide Section 60 support for the second application of the Dr Foster Unit at Imperial to continue the current position as members did not feel there was justification for extending access to another organisation. If this required the Imperial Unit to employ more staff to provide all the relevant expertise then this approach was preferable to extending access to another organisation.

It was agreed to support this application, subject to the usual annual review mechanism, until SUS is able to deliver an alternative service.

Approval is also subject to the following conditions:

- Appropriate contractual arrangements being place with NHS CFH.
- That sensitive information such as sexual health information is filtered out prior to disclosure to Imperial.
- That the Imperial Unit undertakes its own user involvement rather than relying on that of DFI.
- That data is pseudonymised on a rolling 3 year programme.
- Clarification of precisely what data is disclosed to DFI and assurance that it is effectively anonymised.

Action: Secretariat to write to the applicants to inform them of the Advisory Group's decision

8.4 Royal Hallamshire NHS Trust – Ocular Sebaceous Carcinoma (OSC) [PIAG 1-05(e)/2007]

The Advisory Group considered this application for a national prospective study proposed to obtain a contemporary rate of incidence for OSC and to examine the management of Ocular Sebaceous Carcinoma in the United Kingdom. Although very small numbers of patients are involved and therefore it could be argued that consent should be feasible, this could also result in data bias if a case was omitted or

duplicated. It was noted that there was support for the study from the Rare Cancer Forum and that this was a reasonable strategy in relation to patient involvement. It was noted that in terms of seeking consent, there were a substantial number of clinicians involved and that it could take a long time to reach diagnosis.

The Advisory Group were not convinced however that the frailty of patients with advance disease would be a barrier to obtaining consent. It was agreed that further discussion was needed, referred the application, and agreed to invite the applicant to the next meeting.

Action: Secretariat to write to the applicants to inform them of the Advisory Group's decision and invite them to a meeting.

8.5 University of Leeds – Using routine health datasets to evaluate cancer service re-organisation: Current patterns of breast cancer care in the UK [PIAG 2-05(f)/2007]

The Advisory Group considered this application for Section 60 support for a project to evaluate whether the major reforms and reorganisation of UK breast cancer services over the past decade have resulted in improvements in standards, equality of care and improved outcomes. The Advisory Group did not accept the arguments that complete data ascertainment was necessary, nor the argument about causing patients distress. It was also noted that patient involvement was poor and the applicant could have consulted a national cancer charity to test the acceptability of this use of patient information. In spite of these reservations, the Advisory Group agreed this was an important study and agreed to approve this application subject to the following conditions of approval:

- Removal of names within 12 months
- Satisfactory security arrangements

Action: Secretariat to write to the applicants to inform them of the Advisory Group's decision

8.6 NatCanSAT Clatterbridge Centre for Oncology NHS Trust: End of Life Analysis [PIAG 2-05(g)/2007]

The Advisory Group considered this application from NatCanSAT to analyse admissions to hospital and outpatient attendances taken from HES for patients in the last six months of life in order to support the work of the Department of Health end of life committee.

Members were concerned that once again what had been submitted was a very thin application. The condition of approval imposed for other applications that the applicant should improve its user involvement had still not been addressed. Given the number of applications received, the applicant has every reason to have a standing reference group for patient involvement. The Advisory Group agreed to refer the application and to seek a meeting with the applicant with a small group of members

to discuss these issues. Members that volunteered to be involved in this meeting were Professor Sir Denis Pereira-Gray, Dr Peter Rutherford and Dr Fiona Douglas.

Action: Secretariat to write to the applicants to inform them of the Advisory Group's decision

8.7 University of Liverpool _ GEMCAP, a phase III multicentre randomised clinical trial comparing Gemcitabine along or in combination with Capecitabine for the treatment of patients with advanced pancreatic cancer [PIAG 2-05(h)/2007]

The Advisory Group considered this application from the University of Liverpool Cancer Trials Unit, to obtain patient's name and NHS number from research sites in order to confirm patients' date of death from the ONS database.

As this only required limited access to identifiable data to identify relevant patients and as consent had been obtained for participation in the study more generally but that this aspect had not been included within the terms of the consent, the application was approved subject to:

- The destruction of identifiers within 7 months

Action: Secretariat to write to the applicants to inform them of the Advisory Group's decision

8.8 UK Transplant – A service evaluation to determine the rate of transmission of donor malignancy to recipients of solid organ transplants in the UK using data from cancer registries [PIAG 2-05(i)/2007]

The Advisory Group considered this application for Section 60 support to cross analyse the databases of UK transplant with the cancer registries in order to identify all donors with a malignancy and the recipients of organs from those donors and to see whether the recipients went on to develop a donor-type malignancy.

It was noted that the majority of patients would be dead therefore, consent was not an issue for them. Where people were surviving and had perhaps put the transplant behind them, members agreed that it was likely that knowledge of the study was likely to increase the anxiety of recipients although this argument for not seeking consent had not been included in the applicant's argument. It was agreed that this study was essential and that this was one of those rare times when 100% data ascertainment was necessary.

The Advisory Group agreed to approve the application subject to the following conditions:

- That the applicant undertake user involvement
- That the applicant develops a mechanism to take action should particular group(s) be identified as higher risk group and beneficial intervention is possible.
- Clarification of what identifiers need to be retained for analysis or beyond 12

months.

Action: Secretariat to write to the applicants to inform them of the Advisory Group's decision

8.9 Royal College of Surgeons of England Patterns of clinical practice and outcome among patients with oesophago-gastric cancer in England [PIAG 2-05(j)/2007]

The Advisory Group considered an application from the Royal College of Surgeons.

The aim of this application was to create a linked HES-Cancer Registry dataset containing diagnosis and treatment information on English patients with OG cancer. This dataset would then be used to examine treatments patterns and patient outcomes in England. This process is already covered by an existing PIAG approval, this application is specifically for the clinical effectiveness unit at the royal college of surgeons to have access to the dataset in order to analyse patterns or care and outcome amongst patients.

This application was approved subject to confirmation of satisfactory security arrangements.

Action: Secretariat to write to the applicants to inform them of the Advisory Group's decision

9. Information Centre for Health and Social Care

The Chair welcomed Professor Denise Lievesley the Chief Executive for the Information Centre for Health and Social care, to the meeting. Professor Lievesley presented an overview of the work of the Information Centre. The central purpose of which is to facilitate information being at the heart of decision-making throughout health and social care by making available independent, authoritative, comparative data.

It was noted that the Information Centre has had a good relationship with the Security and Confidentiality Advisory Group (SCAG), which has had a monitoring role in relation to the work of the Information Centre. SCAG's role has included acting as gatekeeper for access to sensitive or identifiable data within the large national databases [the National Strategic Tracing Service (NSTS), the NHS Wide Clearing Service (NWCS) and Hospital Episode Statistics (HES)]. It was noted that apart Hospital Episode Statistics the other databases had now been replaced by NHS CFH services e.g. the Personal Demographic Service has replaced NSTS.

Professor Lievesley reported that information security was a high priority for the Information Centre and that they were working closely with the Department of Health's Security Adviser to ensure the relevant information security standards were met. It was noted that information governance within the Information Centre is the responsibility of the Audit and Risk Committee. It was also noted that work was in

hand to ensure the Information Centre meets the requirements of the Statement of Compliance for connection to N3, the new NHS network provided by NHS CFH.

Professor Lievesley highlighted that many of the applications for Section 60 support were for research and that in future it may well be that much research could be undertaken without access to patient identifiable information. She emphasised that there was a need to move incrementally towards pseudonymisation, as there was a need to build trust with the research community with respect to the quality of the data so that researchers could be confident of the validity of results. It was noted that plans had changed from having a single large database for Secondary Uses to a federated model, where more than one centre would hold identifiable information for a range of purposes and that can be provided to others in de-identified form according to the hierarchy of the minimum data necessary for the purpose. The hierarchy beginning with aggregate data, then anonymised, then pseudonymised, with identifiable data being used as a last resort and only with Section 60 approval. Professor Lievesley indicated that her view was there would always be a need for Section 60 approval albeit that the need would be increasingly exceptional. She emphasised that it was important that such decisions were made by an independent body and not the body responsible for managing the data, such as the Information Centre.

Members asked for clarification on the core relationship between the Information Centre and NHS CFH. It was reported that the Information Centre have Service Level Agreements with NHS CFH and that Professor Lievesley has regular meeting with Gordon Hextall, the Chief Operating Officer for NHS CFH. It was noted that the relationship was not solely with regard to SUS but also data quality issues and the Information Standards Board. It was noted that the Department was considering how it was to become more effective as a commissioner of Information Services. It was noted that there was a process of change ongoing with respect to the Department of Health sponsor and that this had not yet been resolved.

Members also sought clarification on the relationship with Dr Foster Intelligence (DFI). It was reported that the Information Centre had formed a joint venture with Dr Foster to form Dr Foster Intelligence. It was noted that the public sector owns half of the shares for this new organisation, which is administered through a joint board whose members are half from Dr Foster and half from the Information Centre. The joint venture exists to provide additional services to the NHS. Professor Lievesley emphasised that this was not an exclusive relationship and that the Information Centre had relationships with other organisations both academic (e.g. NCHOD, Oxford) and private sector bodies (e.g. Newchurch). There was no question therefore about Dr Foster being in a privileged position therefore. She reported that permissions for data access were appropriately managed through Section 60 approvals. She acknowledged that this was not simply a case of having the proper procedures in place but also about external perceptions and acknowledged that Dr Foster Intelligence do have access to information to which others not have access, through their sponsorship of a special

unit at Imperial College. Professor Lievesley reported that she had lawyers advising her on the issue of re-use of public sector information. She emphasised that the Information Centre were neither advantaging nor disadvantaging DFI. It was noted that six Information Centre staff were currently on secondment to DFI. It was noted that the Caldicott Guardian for the Information Centre does not have responsibility for DFI. The Information Centre ensures that ethical practice is being followed through its position on board and that the Information would not wish to do anything that might jeopardise its reputation.

Members welcomed this very constructive discussion with Professor Lievesley and thanked her for attending. It was noted that the Secretariat was working with the Information Governance team within the Information Centre to ensure that as new activities were developed that alternatives to Section 60 support would be explored and if not feasible that Section 60 approval would be sought.

10. Annual Review of the Regulations made under Section 60

The Advisory Group considered a paper on the 2007 annual review of regulations made under Section 60, including reports from the United Kingdom Association of Cancer Registries (UKACR) and the Health Protection Agency (HPA) under their Specific Regulations.

Specific Support Regulations:

10.1 United Kingdom Association of Cancer Registries (UKACR)

The Advisory Group considered the report from the UKACR describing the steps taken during the previous year to improve the way they processed patient identifiable information. The Group warmly welcomed the further progress that had been made in the last 12 months. The Advisory Group recommended that the UKACR continue to receive Section 60 support.

10.2 The Health Protection Agency

The Advisory Group considered the report submitted by the Health Protection Agency and welcomed the work that had been undertaken during the previous year and acknowledged the progress that had been made in reducing the processing of patient identifiable information. The additional information regarding the National Public Health Service of Wales was approved.

Class Support Regulations

10.3 The Advisory Group had previously agreed that each activity carried out under the class support arrangements should be reviewed on the anniversary of the original application receiving PIAG approval. The Secretariat reported to members that they had received reports from 60 applicants and reports from the remaining applicants were expected. The Secretariat reported that the responses received were positive and

addressed the conditions set out by the Advisory Group. Clarifications or extensions were requested by some applicants regarding their continued Section 60 support and these had been reported to the Advisory Group and approved where necessary at each meeting.

10.4 The Advisory Group approved the continuation of the class regulations, as it was apparent that the NHS CFH Secondary Uses Service was still unable to provide a solution in terms of providing pseudonymised data. It was also acknowledged that once this service was fully operational this would reduce the number of applications for Section 60 support but that there would be a continuing need for exceptions to the common law duty of confidentiality for some activities.

11. Contact Point (formerly Child Index) Update

It was noted that no update had been received. It was noted that the security issues had still not resolved. It was agreed the comments and concerns of the Advisory Group should be sent to Contact Point.

Action – Secretariat to contact to Christine Goodfellow, Programme lead for Contact Point.

14. Future meetings for 2007

Wednesday 12th September 2007
Tuesday 4th December 2007