Draft Minutes

PIAG
Patient Information Advisory Group

Meeting held on Tuesday 6 March 2007 at 9.00am

Present:

Members: Professor Joan Higgins (Chair), Professor Mike Catchpole, Dr Tricia Cresswell, 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 Philip Brown (Information Governance Review), Dr Christine Goodfellow & colleagues (Contact Point), Mr Jeremy Thorp (Secondary Uses Service - Connecting for Health), and Mr Roderick Tooher (DH Social Care Information policy)

1. Welcome and Apologies for absence

1.1 Apologies were received from Dr Fiona Douglas.

2. Minutes of last meeting

2.1 Minutes of the previous meeting held on Wednesday 13 December 2006 were agreed to be an accurate record.

3. Matters Arising/Action Points

3.1 The Advisory Group asked that the minutes record the rationale for the decisions about applications in greater detail.

3.2 The responses from the BMA GP Committee and the Healthcare Commission with respect to the issues raised in relation to patient surveys were noted.

4. Secretariat Report

4.1 The Secretariat report was received and its contents noted.

4.2 Annual Report

The draft annual report was agreed in principle. It was agreed that members would provide comments by email and that final approval could be undertaken by Chair's action. It was agreed that a summary report should also be produced based on the full report and approved by Chair's action.

Action – Members to comment on draft Annual report

4.3 Internal representation & review procedure

The draft internal representation and review procedure was received and it was agreed that members would provide comment by email and that the final approval could be undertaken by Chair's action.

Action – Members to comment on draft Internal representation & review report

4.4 Approval extensions

It was noted that the following extensions had been approved by Chair's action: Occupation and Mesothelioma study 1-08(e)/2003 to add another data source to extract the same data items and improve the completeness and validity of data.

PSA and Prostate Cancer Linkage Study PIAG 3-07(l)/2005 for a time extension from 1/2/2007 to 31/12/2007 as it had taken them longer than anticipated to extract and verify the data.

5. Chair's Report

The Chair reported that the MRC commissioned research undertaken by MORI would be launched along with another study commissioned by the Wellcome Trust in Mid-April. [Note from the Secretariat – The launch has been delayed until 26 June 2007].

6. Applications previously considered

6.1 Record Linkage of GPRD data with 1.central (ONS) death certificates 2.Hospital Episode Statistics and 3.Small area Townsend scores (Socio-economic class (SE-class)) resubmitted as PIAG 1-04/2007.

This application was originally considered at the meeting in September 2006. The Advisory Group approved the application in principle but was unable to confirm this decision as the third party intended to carry out the linkage had not been chosen and therefore the security details were not known. The applicant was informed to resubmit the application providing the full security information of the third party chosen. The Advisory Group confirmed its previous approval subject to the Information Centre's security policies and procedures being satisfactory and their formal adoption by the Information Centre's Board.

Action: Secretariat to inform the applicant and to ascertain assurance on the security arrangements.

7. Fast track applications

7.1 Strategic Reconfigurations of Haemophilia Consortium - Croydon PCT on behalf of the Pan Thames Haemophilia [PIAG 4-06(FT4)/2006]

This application from Croydon PCT on behalf of the Pan Thames Haemophilia Consortium was to analyse patterns of admissions as part of a detailed needs assessment, which would be used to reconfigure services, and for clinical audit.

This was approved subject to the following conditions:

- Confirmation of appropriate data destruction.
- Confirmation that age / age bands and ethnicity will only be held for the 2-year duration of the project. Age bands should be used if sufficient for the analysis being undertaken.
- Clarification of what geographical identifiers would be retained beyond the two-year period.

7.2 Network of Services to provide care for persons with haemoglobinopathies - NHS Sickle Cell and Thalassaemia Screening Programme, GKT Hospital Trust [PIAG 4-06(FT5)/2006]

This application from the NHS Sickle Cell and Thalassaemia Screening Programme, GKT Hospital Trust was to analyse patterns of admissions as part of a detailed needs assessment to be used to develop an appropriate network of services. This was approved subject to the following conditions:

- Confirmation of which geographical identifiers would be held for longer than the initial data collection period.
- Satisfactory security arrangements.

7.3 BPSU study: Genital Herpes in Children Under 11Years of Age Presenting to Secondary Care - Norfolk and Norwich University Hospital [PIAG 4-06(FT6)/2006

This application from Norfolk and Norwich University Hospital was to look at the rare condition of Genital Herpes in prepubertal children. Paediatricians currently have very little evidence on which to base an opinion on possible mode of transmission, yet their advice is central as to whether or not a child protection investigation proceeds. This study aims was to provide data on the incidence of genital herpes in young children in the UK and Ireland, and describe the clinical features associated with different possible modes of transmission. This was approved subject to the following conditions:

- Reduction of Date of Birth to age at presentation following linkage and validation.
- Confirmation in 12 months as to whether data collection period is being extended.

7.4 The success rate of fissure sealant therapy - University of Sheffield [PIAG 4-06(FT7)/2006

This application from the University of Sheffield looked at retrospective case note review of fissure sealants placed by dental care professionals (DCPs) or dentists. The study's aim was to obtain preliminary data on the effectiveness of fissure sealants placed by dentists or DCPs and to determine the variability of effectiveness of fissure sealants placed in real life (everyday) conditions. This was approved subject to the following conditions:

- Names being removed after a 4 week data validation process
- Removal of postcode within 3 months
- Confirmation of satisfactory security arrangements with regards to secure data transfer and destruction.

7.5 Development of a Paediatric Track and Trigger System: Validation of the Paediatric Advance Warning System (PAWS) - Paediatric Epidemiology Group, Centre for Epidemiology and Biostatics, University of Leeds [PIAG 4-06(FT8)/2006]

This application from the University of Leeds was for a research nurse to access patient notes to extract relevant clinical information in order to evaluate the PAWS system, which aims to identify children who might be deteriorating and in need of further treatment. This was approved subject to the following conditions:

- Satisfactory security arrangements
- That hospital and ward code are removed once type is allocated and date of death is converted to age at death
- That the patient information leaflet is amended to make explicit that a research nurse and not someone who is part of the clinical care team will be accessing the notes and that patients have the right to opt out if they have concerns.

8. New applications

8.1 Human Fertilisation and Embryology Authority (HFEA) – An investigation of the risk of cerebral palsy following conception by assisted reproductive technology (ART) [PIAG 1-05(b)/2007]

The Advisory Group considered this application for Section 60 support to allow the HFEA to receive data from four clinical databases, undertake necessary linkage and provide an anonymised dataset to researchers. This linkage would create one of the largest study datasets available in the world to examine the relationship between ART and cerebral palsy.

The Advisory Group noted that the basis of consent was different for the 3 cerebral palsy databases, for example the North of England database is fully consent based whereas the Northern Ireland database no consent is sought. The Advisory Group

agreed that the Chair should write to the NI Privacy Advisory Committee to raise this issue with them.

Action – Chair to write to NI Privacy Advisory Committee.

It was also noted that no user involvement had been undertaken for this study and it seemed that the applicant had misunderstood the concept of user involvement. User Involvement does not necessarily require the involvement of individuals who are part of the cohort under study, but people whose condition or circumstances are similar, and/or organisations or groups representing the interests of those affected by the condition being investigated. This would not contravene HFEA rules. The Advisory Group felt that it would be beneficial to involve users as one of the aims of the study was to inform professionals and the public of any potential outcome risks associated with ART conception, the Group felt it would be useful to obtain some general views on the study design and publication of results / information.

The Advisory Group agreed that this was a valuable study and noted its similarity with the previously approved study into congenital anomalies. It was agreed that there was significant public interest justification for it to go ahead and so agreed to approve the application subject to the following conditions:

- Assurance that the HFEA would be taking steps to ensure that data disclosed could not be linked with other data held by the NPEU in Oxford. (check if responded to on query sheet omit from the list)
- A generic application being made for future linkage work as it is apparent that the same identifiers are needed for linkage.

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

8.2 Linkage of National Cancer Registry data to national Hospital Episodes Statistics (HES) data [PIAG 1-05(c)/2007]

The Advisory Group considered this application from the London School of Hygiene and Tropical Medicine to allow linkage of Cancer Registry data to HES data in order to explore the influence of clinical parameters such as surgical procedures, other treatment, and co-morbidity on geographical and socio-demographic differences in cancer survival.

This is intended to be a very large study, including all patients with a diagnosis of cancer between 1989 – 2005, resident in England aged 15-99 at diagnosis, which would total several million records. The Advisory Group agreed that consent would not be feasible for this study because of the large numbers involved.

The Advisory Group was concerned that, in essence, this would involve the disclosure of the entire HES database for this period to the LSHTM and members were concerned that this may unnecessarily duplicate the role of the Cancer Registries. The Advisory Group recognised that there was an issue with needing to de-duplicate data across multiple registries, which related to the same individuals but had moved area. The Advisory Group also recognised that the researchers involved in this study had impeccable credentials in relation to the quality of research undertaken and

responsible handling of data. The Advisory Group was also concerned at the proposal for this to be an ongoing study although the application was only made for three years in the first instance. Members wondered whether it was feasible for the researchers to work with the staff at the Information Centre and/or Cancer Registries to ensure data quality and to develop an exit strategy from Section 60 approval.

The Advisory Group was also concerned that this was another application supported by Cancer Research UK which had only token user involvement and that there had been little evidence of a cultural shift towards more meaningful user engagement. The Advisory Group proposed that CRUK, as the sponsoring body, should consider establishing an Advisory Group with representatives from different cancer organisations (in particular those more directly engaged with caring for cancer patients).

In spite of these reservations, the Advisory Group agreed this was an important study with the likelihood of delivering significant benefits for patients with cancer, identifying and quantifying the factors relevant to cancer survival at a population level for targeting interventions more effectively to reduce inequalities and improve survival.

The Advisory Group therefore agreed to approve the application for 3 years, but with the proviso that approval should not be perceived as setting a precedent. Approval was also subject to the proviso that an exit strategy via the NHS CFH Secondary Uses Service or through the Cancer Registries should be developed. If this proves to continue to be unfeasible then the Advisory Group will consider extending the Section 60 approval. This support is also subject to:

- Improved user involvement, as outlined above
- Confirmation that this study has ethical approval
- Satisfactory security arrangements

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

8.3 Department of Health – National Patient Choice Survey [PIAG 1-05(d)/2007].

The Advisory Group considered this application from the Department of Health to allow Ipsos MORI to take over the processing and administration of the National Patient Choice Survey in order to improve response rates and reduce overheads. Previous waves of the survey have resulted in poor response rates, in particular from ethnic minority groups.

The Advisory Group had concerns with this application; in particular, that it was unclear how the proposed method would improve coverage among ethnic minority groups as the Advisory Group were not convinced that this approach would be effective and therefore remained to be convinced of the patient/public benefit of the disclosure in this instance.

The Advisory Group were concerned that there had been a misunderstanding in relation to user involvement in this application, in that the acceptability of disclosing

information for this purpose and the proposed method involved did not appear to have been tested.

The Advisory Group referred the application but agreed that provided the responses to the following concerns and questions could be answered satisfactorily, that the Chair could approve the application on behalf of the Advisory Group, and so it should not need to wait to be resolved at the next meeting.

Other aspects that required clarification were:

- Confirmation of what patient involvement (specific to this study) has been undertaken and agreement to improve if necessary
- Clarification whether the letter to patients will be on Ipsos MORI or Trust letter headed paper
- Clarification of the proposed exit strategy
- Confirmation that hospitals will review the data extract prior to disclosure to ensure non-disclosure of stop noted patients or where there are other sensitivities involved e.g. recently bereaved patients etc
- Clarification regarding data security, in particular data transfer
- Confirmation in 12 months that there is added value/benefit is continuing with this approach and any changes made as a result of this pilot

Clarification in 12 months what has been demonstrated to be a reasonable but minimal time for retention of identifiers.

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

8.4 CONDUIT 3 (Cutting out needless death using IT): Primary Care Disease Registers in Wandsworth [PIAG 1-05(e)/2007]

The Advisory Group 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.

The data collection began in 2001 and it is unclear what has been happening regarding consent or use of identifiable information since then and this was something that required urgent clarification.

One of the reasons given for not obtaining consent was the large numbers involved (approx 15 thousand patients) but it was unclear how many GP practices were taking part and therefore the number of patients per practice was not known and could be a manageable figure.

The Advisory Group was unpersuaded by the arguments presented in the application, as there was no evidence they had tested the feasibility of obtaining consent, nor of

the feasibility of longitudinal linkage being undertaken within the practice following initial linkage and allocation of a study number. The Advisory Group were concerned that no patient information materials had been created or used to date, and did not approve the application for these reasons. The Group did agree to invite the applicant and the Caldicott Guardian (data controller) from the PCT to the next meeting in order to clarify some of the queries.

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

8.5 National Burns Injury Database [PIAG 1-05(f)/2007]

The Advisory Group considered this application for Section 60 support to allow linkage of HES and hospital data in order to analyse the incidence and geography of burn injury in England for the purpose of planning and monitoring future service configuration.

The Advisory Group agreed that this was a legitimate research question and that there were significant benefits to be gained from the research going ahead. The Advisory Group were concerned that this application had not been well presented or sufficiently well defined in the data it was seeking, but recognised that considering both the numbers involved (between 50,000 and 200,000) and the fact that this was a single extraction of retrospective data and not leading to long term follow up that requiring consent to be sought would be disproportionate in this instance. Members had also felt that the response to user involvement however was weak. Whilst patient groups had been involved at a high level, no patient involvement had been conducted at patient level and the Group felt, considering this application was regarding service delivery, that engaging with patients would be beneficial to ensure that the needs analysis meets patient needs as well as service needs.

Additional concerns were that data would be transferred securely and destroyed appropriately.

The Advisory Group referred the application as it stands but that they were likely to approve a revised application subject to the following:

- Better definition of both the identifiers and data required.
- Appropriate supporting documentation including security policies in particular addressing secure transfer and data destruction methodologies.
- How they will address the issue of future data collection.
- Clarification of an exit strategy and when identifiers will be reduced/removed from the dataset

It was agreed this could be done via Chairs action outside of the meeting and was not required to come back to the next meeting provided these issues had been appropriately addressed.

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

8.6 HES and STATS19 one to one matching project [PIAG 1-05(g)/2007]

The Advisory Group considered this application from the Department for Transport for a study, matching road casualties admitted to hospital (HES) data with casualties recorded by the police (STATS19) data with the aim to assess whether there has been a change in the levels of reporting of road casualties to and by the police.

The Group agreed that there would be significant public interest in any research that would lead to reducing the number of road traffic accident casualties. It was unclear; however, how these benefits would be achieved through this study. Members felt that this was more a check on the accuracy of the STATS19 database than a valid medical purpose.

The Group also questioned whether the Information Centre could undertake the linkage of behalf of the applicant. It was unclear whether this route had been explored.

The Advisory Group did not approve the application and invited the applicant to resubmit a revised application to the next meeting providing further clarification of the following:

- Clarification as to whether the IC could undertake the linkage of behalf of DfT
- Improved user involvement
- Clarification of how this research provides patient or public benefit in order to satisfy the Advisory Group that this falls within medical purposes.

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

8.7 Yorkshire and Humberside Haematology Network Register [PIAG 1-05(h)/2007]

The Advisory Group considered this application from the University of York, to utilise Section 60 for certain patients where it has proved difficult to obtain consent. The Register currently attempts to obtain consent for all patients newly diagnosed with a haematological malignancy in the Yorkshire and Humberside region however there are certain groups that have been difficult to reach in order to obtain consent. These include patients that are not treated by haematology services, but by other secondary or monitored via primary care with no active treatment.

The Advisory Group agreed with the approach in general, and recognised that the applicants we trying to obtain consent wherever possible however felt that in some circumstances more could be done to obtain consent such as with those in regular contact with non-haematological services.

There was also concern that this study was also intending to retain tissue samples and the Advisory Group wanted to make clear that this was outside of its remit and that any Section 60 support given would not cover the retention of tissue samples in identifiable form without consent.

The benefit to this patient group would be the robust auditing of care against national guidelines. The results will be used to identify important issues for patient care in the

Region. It could also inform both the refinement of the national guidelines themselves and potentially patient choices about care both regionally and nationally. Research using pseudonymised data from the register will also seek to identify the risk factors for both the development and progress of haematological malignancy, thus additionally serving the wider public interest.

Although the general position of the Advisory Group is that inclusion on a disease register, outside of the care provider, should be undertaken with patient consent, members were persuaded, at least in part, that there was a strong patient benefit to this activity and that there was a clear exit strategy of consent. The Advisory Group therefore agreed to provide partial support under S60 to enable the research nurses access to data in order to identify the relevant patients from whom to seek consent. The approval would also cover data extraction for deceased patients and for those too ill to provide consent but that more should be done to obtain consent from the 'hard to reach' groups and the Section 60 approval was limited in this regard to their identification in order to seek their consent.

This approval was subject to:

- Robust mechanisms established to ensure that patient dissent was respected and that where this was the case that clinical staff extract data to HILIS for clinical purposes.
- Confirmation that only effectively pseudonymised data is disclosed to York University for analysis
- Continued user involvement with patient and carer groups with relevant similar Haematological conditions.
- Consent is sought from those treated by other specialties or monitored in primary care.
- Consideration given to compliance with the provisions of the MCA with respect to patients lacking capacity.
- Clarification that tissue samples will only be held with consent or in anonymised form.
- Satisfactory security arrangements.

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

8.8 Inclusion for DSPD: Evaluating Assessment and treatment.

This was a resubmitted application for a project evaluating treatments and outcome measures for dangerous and severe personality disorder (DSPD). Section 60 support was requested for access to records of patients who are referred but not admitted to the unit. The application was not approved at a previous meeting for a number of reasons but primarily due to the presumption that DSPD patients would be likely to dissent as a direct result of their disorder although not lacking capacity and the breadth of the approval that was sought, without testing the feasibility of obtaining consent.

This application was a more carefully defined application, requesting short-term access to records in order to extract limited identifiers for those patients not admitted to the specialist units and consent being sought from those who were admitted.

The Advisory Group were impressed by the work undertaken by the research team to engage with forensic patients and prisoner groups and the fact that this had led to changes in the study design. The Advisory Group felt that this demonstrated admirably how it was possible to work with difficult groups.

This study would provide benefit to both this patient group and the wider public. Currently there is no evidence base for the care and treatment of this group of patients and considerable professional doubt over whether any treatment for DSPD would be effective. It is clearly then important that such treatments are appropriately evaluated and patients for whom such treatments offer no benefits are identified to protect them from ineffective treatments. There is also a wider public benefit in the effective treatment of such patients to reduce the likelihood of re-offending and to assess the risk they may pose to the public on release.

Overall, the Group felt that the quality of this revised application was excellent and agreed that the benefit to both this patient group and the public outweighed the breach of confidentiality in these circumstances and approved the application.

The Group also noted that any support given should only be for where is not practicable to obtain consent and not to override the wishes of those who have dissented.

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

8.9 National population based case control study of the genetic, environmental & behavioural causes of breast cancer in men [PIAG 1-05(j)/2007]

The Advisory Group considered this application for Section 60 support to identify all male patients aged between 18-79 with breast cancer between 2005 – 2012 in order to seek consent from the relevant cohort. It was noted that this application was very similar to a study into Leukaemia (PIAG ref 4-07(q)/2002). As this involved data about very large numbers in order to identify the relevant cohort, it was recognised that consent would not be practicable. It was also clear that there was a clear exit strategy via consent.

It was noted that controls would be recruited via the index patient and not directly by the research team. Members also welcomed the efforts made to engage with patients through interviews conducted as part of the pilot study.

The potential benefit of the study would be to find potentially preventable causes of breast cancer in men, and with a view to considering the relevance of these for the aetiology of breast cancer in women. In particular, the study would evaluate the risk of breast cancer in female relatives of men with breast cancer according to genotype in order to provide more accurate risk estimates for such women. The study would also seek to compare the pathology of male and female breast cancers.

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

- That data about patients who withhold consent is removed immediately.
- That data about non-responders is removed within 7 months of the final invitation.

The Advisory Group also suggested that consideration be given to how to ensure that there is no coercion from family members with respect to the recruitment of controls.

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

8.10 Child Height and Weight surveillance [PIAG 1-05(k)/2007]

The Advisory Group considered an application from the Department of Health for the Information centre for Health and Social Care to obtain identifiable data from the child height and weight surveillance measurement being undertaken by PCTs in order to conduct a national analysis of the data.

The Advisory Group were uncertain about the degree of added benefit this would provide to local or regional level analysis with aggregate data reported nationally. The Advisory Group were also concerned that this represented a significant departure from normal child health surveillance practices, which only involves reporting of aggregate data. Whilst there are precedents for other public health surveillance involving patient level identifiable data these have S60 support, are related to communicable disease and other risks to public health, and are undertaken by the HPA where there is often an issue about urgency.

Members were also concerned that this application appeared to be with the precise intention of minimising parental dissent both to the weighing and measuring and to the disclosure to a national database by having an opt out rather than an opt in approach. Whilst the Advisory Group was sympathetic to the desire to obtain good data and therefore of the need not to follow a consent model for the measurement, this presented considerable difficulty with respect to disclosure of data. It has long been one of the Advisory Group's key principles that S60 is not to be used with the intention of over-riding patient dissent but only to allow that consent need not be sought where it is impracticable to do so. It is debateable whether consent in this situation is feasible, as information will be sent home to parents via the school although with no guarantee that the letter will be received by all parents.

The Advisory Group were also concerned that there was a significant gap between the advice given at a national level with respect to information materials given to parents and the practice at a local level. The Advisory Group did not feel that the template for information to be included in a letter was adequate to address this and felt that a national leaflet with a template letter should be provided which could then be adapted for local variation.

The key data item in question was the postcode, which has been requested in full so that the lower Super Output Area could be calculated for deprivation scoring

purposes. This level of data is however still likely to be identifiable at least in some areas.

Mr Kirwan advised members he believed there had been legal advice stating that consent was required. In light of this, the Advisory Group did not reach any firm conclusion on this application but agreed to refer until the legal advice could be clarified.

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

[Note by the Secretariat: - The legal advice to which Mr Kirwan had referred, related to where information would be given to parents about height and weight, in effect turning this activity into screening. It is clear that screening requires consent and in such circumstances, there would be no difficulty with obtaining a second consent for disclosure to a national database. The Secretariat subsequently sought further legal advice related specifically to the activity as presented in the application. The conclusion of this advice was that it was up to the Advisory Group to determine the legitimacy of this activity or otherwise.

Following the meeting, the Advisory Group considered the issues related to this application via email and agreed to refer the application, as presented, for the following reasons:

- some areas have already collected this data on the same basis as last year.
- because the Group were concerned that this was using the powers under S60 with the intention of over-riding the dissent of parents and children. This would be against one of the Advisory Group's key principles.
- because it was not apparent, that due consideration had been given to the Fraser competence of 11 year olds and how that would affect both the measuring and disclosure of information.
- because the Group did not consider there was sufficient time to develop appropriate information materials for parents and children and felt that the template for a letter did not provide adequate assurance given evidence of such standards not being implemented at a local level.
- And because in spite of ongoing discussions over the last 18 months with the Obesity team within the DH, a proposal has again come forward at the last minute and which has not been thought through sufficiently.

It was proposed that in light of this only the same data as last year should be collected albeit perhaps using the Information Centre for Health and Social Care in place of the UNIFY system, although there are outstanding issues with assurance about the security policies for the IC which need to be resolved. The Advisory Group might be willing to approve this for next year's data collection if satisfactory appropriate information materials can be developed and assurance as to the processes followed at a local level. Some comments on the specific nature of such information materials were made and the Secretariat was asked to convey these to the applicant.

Subsequent to this, an alternative proposal was made which involved staggering the disclosure of data to the Information Centre with the postcode being submitted first so that deprivation scoring and lower level Super Output Area could be assigned and matched subsequently to the other data, but with the postcodes being destroyed prior to disclosure of the clinical data. On this basis, it was very borderline as to whether Section 60 approval was needed as the risk of such information generally being identifiable was small. It was agreed by Chair's action to provide Section 60 approval on this very limited basis following consultation with members by email.]

9. Secondary Uses Service – Connecting for Health

The Chair welcomed Mr Jeremy Thorp to the meeting. The purpose of the discussion was for Mr Thorp to provide a brief update to the Advisory Group on the development of the Secondary Uses Service and to discuss issues for the forthcoming revised application in June.

Mr Thorp reported that the implementation of the technology to support commissioning had occurred in November 2006 with the system going live in early December and the contract for the NHS Wide Clearing Service being terminated at the end of December 2006. It was noted that there had been an adjustment of some of the timelines to incorporate data streams to satisfy clinical audit and other needs because of the prioritisation of 'Payment by Results' (PbR) and 18 week waits analyses by the Department of Health. It was noted that these would be delivered in 2007.

Mr Thorp sought to provide assurance to the Advisory Group about the Information governance mechanisms in place, specifically that there were Role Based Access Controls (RBAC) in place for online services and that there were a restricted number of users at present and a data handling protocol which they were required to follow.

It was noted that a number of initiatives were underway to improve data quality including use of the 'xml' format, which would facilitate improved validation checks within SUS, and that data would be refused until the data quality met the required standards. Mr Thorp highlighted that the National Patient Safety Agency was taking forward the use of the NHS number as a safety issue and which should improve use of the NHS number. He acknowledged that a number of issues had arisen following the reconfiguration of PCTs relation to organisational codes but that these were being addressed.

It was noted that new versions of the Commissioning datasets were currently undergoing approval by the Information Standards Board and it was anticipated that these would be implemented within the system in the autumn along with Choose and Book referral information.

Mr Thorp reported on a number of initiatives to strengthen further both the work of and information governance arrangements around SUS. These include:-

i. The Care Record Development Board (CRDB) Secondary Uses sub-group which is considering how best to utilise the data within SUS for secondary purposes whilst ensuring that the boundary of confidentiality is maintained other than where consent has been obtained or there is another lawful basis for access to identifiable data.

ii. A series of simulation projects are being undertaken in conjunction with the UK Collaborative Research Council (UKCRC) to test and identify what SUS needs to deliver to facilitate different types of research. The four simulator projects are to support clinical trials, surveillance studies, cohort studies, and observational and epidemiological studies.

iii. Pseudonymisation pilots have also been undertaken to identify issues for users within Hospital Trusts, PCTs and shared informatics services. The report from this makes it clear that there is still some way to go to win the hearts and minds of users with respect to the robustness and usefulness of pseudonymised data. The testing of the pseudonymisation tools undertaken so far had however been successful.

It was also noted that the pilots had identified a number of activities where identifiable data may be needed or was unavoidable e.g. for highly specialist commissioning which would involve very small numbers of patients, and for geographical analysis which still requires postcode. The importance of ensuring that users have confidence in the pseudonymised data was perceived as vital by NHS CFH to ensure that alternative unregulated data flows did not continue or start.

NHS CFH was seeking to address users' needs for data through increasing the provision of access to aggregate data. It was also proposed to improve access by organisations to data about their own patients and where pseudonymised extracts were used that different pseudonyms would be used for different organisations so that data could be linked longitudinally but not cross-linked with other datasets held by other organisations, as the pseudonyms would not match.

To enable pseudonymisation to be implemented effectively, the system needed to remove the need to check a patient's practice or PCT (so accurate coding of data was imperative). There was a need to support business processes that required data before pseudonymisation was implemented and that this would require legitimised access to patient identifiable data by a limited number of PCT or other staff to validate the data quality. SUS would also need to demonstrate that it is able to cope with a large volume and scale of external linkage requests.

iv. It was noted that there was a tension between RBAC being straightforward enough for national roll-out across the NHS and having it sufficiently precise to provide robust but also useful control for SUS. It was noted that

consideration was being given to how the specific requirements for SUS might be delivered.

The Advisory Group asked for more detail about the extent to which training was a requirement of registration. Mr Thorp responded that all users had to go through registration and although training cannot be enforced, it was expected as part of the registration process.

The Advisory Group asked for clarification about when it was envisaged that the move across the pseudonymised data would be made and whether this would be a step change or a staggered approach. Mr Thorp responded that it was felt that a step change would be needed to provide assurance that the encryption code for the pseudonyms was safeguarded and that the current target date for this was the end of 2009.

The Advisory Group also asked for further clarification about the relationship between NHS CFH and the Information Centre, specifically which organisation would be responsible for the management of access to identifiable data and for determining access controls. Mr Thorp clarified that the Information Centre would be responsible for managing the process through which access would be enabled but that there were clear protocols in place and tools to ensure what is applied with respect to access controls.

Following the discussion with Mr Thorp the Advisory Group considered what other information would be useful in consideration of the revised S60 application in June. It was agreed to ask for further information about:

- The control provided through RBAC.
- The relationship and boundary between the differing roles of NHS CFH and the IC.
- A specific documentation of progress on the conditions of approval set for the previous application
- Guidance issued or to be issued to the NHS on commissioning.
- Detail about any particularly sensitive data items within the new version of the CDS.

10. Contact Point (formerly the Child Information-sharing index)

Mrs Christine Goodfellow, the Project Director for Contact Point from the DFES came to present the proposals for Contact Point to the Advisory Group with a view to beginning discussions about any issues of concern to the Advisory Group. Contact Point was described as a tool to enable practitioners to verify the identity of a child quickly and to be able to contact one another easily to share relevant information about children who may be receiving or in need of services. It is not intended that

Contact Point be any more than a directory of professionals responsible for the care of a child and will not hold case or assessment information.

The core dataset will include basic demographics about every child in England, name, address, date of birth, sex, parent or carer's contact details. It will also include the name and contact details of the child's GP, school, midwife, health visitor or school nurse (as appropriate for the age group). These data items will be stored on all children. Additionally it is proposed that where there is also involvement by a youth worker, social worker, Special Educational Needs Co-ordinator or Consultant that this will also be included on Contact Point. Other data items will include basic details of common assessment frameworks where they have been undertaken, who the lead professional is, a flag that a particular professional has 'information to share' and where action has been taken a flag to indicate this also again with the responsible professional as the author. No consent will be sought to include these data items.

Where a child is also receiving care from sensitive services i.e. sexual health, mental health or substance abuse services, the details of their care professionals will only be included on Contact Point with the child's consent.

Mrs Goodfellow sought to provide re-assurance to the Advisory Group that there would be robust information governance controls around access to this data.

In addition to high standards of system security, which have been agreed with the NHS CFH Chief Technology Officer, it has also undergone independent accreditation. There will be a two factor authentication process and user registration controls including Criminal Record Bureau checks, audit trails to identify potential misuse and appropriate governance mechanisms in place.

Mrs Goodfellow reported that records would be retained until 18 and then archived for six years prior to being deleted. Consideration was currently being given to extending retention of records to the age of 25 for particularly vulnerable young people but that this would only be undertaken with consent. It was also noted that there would be particular safeguards around shielded records in line with cross government policy. This would include children in witness protection programmes and similar circumstances where their location needed to be protected. It was noted that the policy for how to handle situations arising in A & E had been agreed that this was a matter of professional judgment.

It was noted that there had been user involvement with children to find out their views on the proposals for Contact Point and that there is a 16 year old representative from the NCB on the Board for the project and who had been very much against the project initially but who had been reassured by the pilot.

The Advisory Group raised a concern about the security arrangements, and about the fact that the older children from about the age of 14 onwards would be competent, in most instances to decide whether their details were included on Contact Point. The Advisory Group acknowledged that there was a statutory basis for Contact Point to

have this data but agreed that this created a certain amount of discomfort particularly for the 16+ age group.

The Advisory Group also sought clarification about the flags and the speed of update of these i.e. if a child goes through a period of crisis, how long after it has finished would the system be updated. Mrs Goodfellow responded that data would be retained for a year after the close of an episode of care but that there was scope for this to be varied according to professional judgment.

The primary reason for seeking the view of the Advisory Group on the proposals was because NHS data would be used to populate Contact Point. The Advisory Group agreed that it would provide further comment by email to the Secretariat to be collated and passed to Mrs Goodfellow.

Action – Members to send further views to the Secretariat for collation.

11. Health and Social Care Information Boundary

The Chair welcomed Mr Roderick Tooher to the Advisory Group. Mr Tooher introduced his area of work for social care information policy within the Department, which was based on the white paper which had proposed that health and social care records should be brought together to support integrated working between health services and social care services. He highlighted that his work focussed on adult social care and that children's health and social care came within the purview of the Department for Education and Skills. Mr Tooher reported that a single information-sharing protocol had been mooted but that it was recognised that this May well not be practicable or appropriate in all circumstances.

During discussion, the following issues were raised:

- Information-sharing protocols need to be appropriate to the circumstances and therefore a single protocol was unlikely to be workable.

- Whilst such protocols would be necessary, they would not substitute for individuals understanding the implications of such information-sharing such as with the standard assessment protocol and understanding where the boundary lies between NHS continuing care which is free at the point of care and social care which needs to be paid for.

- Current practice involves inappropriate disclosures not only from the NHS to Social Care but also from Social Care to the NHS e.g. details of personal finances being passed to the NHS which is then used to disadvantage individuals who are perceived to be able to afford to pay for social care and therefore are not deemed to qualify for NHS continuing care.

- There needs to be much better information-giving to individuals before undertaking the SAP process. This is underpinned by the requirements of the MCA.

- In relation to an integrated health and social care record there are issues of ownership, would it be a health record into which social care information is put or a social care record into which health information is put. If it is jointly owned that raises the question of who the data controller is, how is the transfer/sharing of confidential data to be managed. There are different rules in relation to Subject Access requests in relation to these different types of data, how is this to be handled?

- The consent process had been described as a process and not as an event. Whilst this is accurate in that there is an ongoing need to ensure data sharing is within the terms of the consent given, it needs to be made clear that this does not leave scope for ambiguity in interpreting whether or not consent has been given.

Mr Tooher responded that in relation to e-SAP there was a broad based steering group with oversight for the Common Assessment Framework, which included representatives from not only the health and social care sectors but also patient groups. He also reported that any social care users for the new systems within Connecting for Health had to sign up to the statement of compliance necessary for connection to N3 and to meet the requisite standards as demanded by the Information Governance toolkit. Mr Tooher agreed that assessment was not just something that was done to the patient but that the patient also had a role. He agreed to raise the financial information issue with colleagues in social care and indicated that this showed a need for training for staff to ensure that information was only shared with the consent of the patient / service user.

12. Information Governance Review Update

The Chair welcomed Mr Philip Brown who had attended to update the Advisory Group on progress in relation to the implementation of the Information Governance Review. Mr Brown reported that the earlier opportunity to introduce legislation that would provide a statutory basis for the National Information Governance Board was likely to be autumn 2007, it had been agreed with the minister that the Board would be developed initially as an internal advisory body. As a consequence of this, there was a need to discuss the relationship between the proposed Board and the Advisory Group. It was noted that there had been some initial discussion with the Chair but that further discussions would be needed once the revised proposed Terms of Reference for the Board had been circulated to the Advisory Group for comment. Mr Brown undertook to provide this for circulation as soon as practicable.

13. Outcome of the Awayday discussion

13.1 During the Awayday, members had discussed two issues: that of identification of cohorts and consent. Following these discussions, draft documents will be developed to provide guidance to researchers and healthcare professionals on these topics. The Advisory Group agreed to have an evening meeting, preceding the next Advisory Group meeting to discuss two further topics. The next Advisory Group meeting had therefore been moved to Tuesday 12 June to accommodate the evening meeting on 11th.

Action – Secretariat to develop draft guidance on the identification of cohorts and consent.

14. Future meetings for 2007

Monday 11th & Tuesday 12th June 2007
Wednesday 12th September 2007
Tuesday 4th December 2007