Ethics and Confidentiality Committee (ECC) Meeting – Thursday 6 December 2012

Members:

Dr Andrew Harris (Chair), Dr Mark Taylor, Mrs Pauline Brown, Dr Tony Calland, Dr Robert Carr, Dr Patrick Coyle, Dr Tricia Cresswell, Dr Fiona Douglas, Mr Colin Harper, Professor Julia Hippisley-Cox, Ms Gillian Wells and Mr Terence Wiseman.

In attendance:

Dr Alan Doyle *(NIGB Director),* Ms Natasha Dunkley *(Approvals Manager),* Ms Claire Edgeworth *(Deputy Approvals Manager),* Mr David Evans *(Information Commissioner's Office),* Mr Martin Frowd (*Senior Business Support Officer*), Mr Mathew Fry (*NIGB Operations Manager* item 6), Mr Richard Ciencala (*Department of Health*)(item 1), Dr Alison Daykin (*Department of Health*)(item 1), Mr James Freed (*Department of Health*)(item 1), Mr Jamie Waterall (*Department of Health*)(item 1), and Ms Dawn Foster (*Health and Social Care Information Centre)*(items 2-3).

Apologies:

Apologies were received from Ms Alison Emslie, Mr Stephen Hinde, Dr Jane Kaye and Mr Chris Wiltsher.

1. Healthcheck

This discussion item was framed by a briefing paper that set out a request for advice, background information to the programme, proposed models of delivering the Health Check and information on Data Protection Act 1998 compliance. It triggered extensive discussion within the Committee and they welcomed the helpful comments from representatives. However, the Committee agreed that following general discussion of the briefing paper and applicant comments that significant work would need to take place for an application to meet the minimum threshold of the requirements of the Health Service (Control of Patient Information) Regulations 2002.

The paper indicated that the NHS Health Check is a universal programme for approximately 15 million eligible people in England between the ages of 40-74, that will assess risk of heart disease, stroke, kidney disease and diabetes and will support people to reduce or manage that risk through individually tailored support and advice. The programme is implemented locally, currently by primary care trusts where approximately 55% deliver the service using mixed models, and requires that the eligible cohort are systematically contacted and offered this service. As the programme is a preventative one, only those without previously diagnosed heart disease, kidney disease and diabetes are eligible for invitation. These need to be identified so that the Health Check is offered only to the relevant population.

Due to changes contained within the Health and Social Care Act 2012, responsibility for commissioning various public health activities will transfer to Local Authorities from 01 April 2013. This is likely to involve changes to how the Health Check is delivered. The paper indicated the following key messages and rationale for the potential application:

1. The identification and exclusion of the applicable population, invitation process and care delivery service could be managed in part or full by a third party supplier.

2. Delivery of the Health Check requires identifiable clinical and demographic information.

3. Patient records held by general practice contain the relevant information to enable the Health Check to be carried out.

4. GPs were stated not to be cooperating with the process in terms of releasing patient information for those eligible for the Health Check to commissioning organisations, or third party providers

5. The explanation for this lack of cooperation was stated to potentially include information governance concerns, time constraints, remuneration or concerns over the clinical benefits of the programme; the paper sought advice on the information governance concerns only.

6. The paper set out four different models and data flows that could take place from April 2013. These would differ depending on the model chosen, participation levels by GP practices and commissioner choice on how they wish to contract different parties to deliver. These models were listed as follows:

- Model 1 - General practice identifies the eligible cohort, sends out invitation letters, undertakes the check, any required additional follow up and records the data on the patient record.

- Model 2 - Local authorities hold the eligible cohort and issue invitations allowing individuals to contact a number of providers and book their NHS Health Check. Where an alternative provider undertakes the check, the outcome is sent to the GP and the GP ensures any appropriate follow up action is undertaken e.g. testing to confirm/ dismiss a diagnosis.

- Model 3 - Local authorities hold the eligible cohort and provide lists to alternative providers who send the invites and undertake the checks. The outcome of the check is sent to the GP and the GP ensures any appropriate follow up action is undertaken.

- Model 4 - In some circumstances the entire service is commissioned from a third party who identifies the eligible cohort and issues invitations.

The briefing paper also sought advice explicitly on the following aspects: whether legal support is suitable for the transfer of data; advice on controls, a potential national cohort management system to be developed in future, and advice for PCTs and Local Authorities.

Within the framework of the Health Service (Control of Patient Information) Regulations 2002, the ECC considers the balance of potential harms to trust in confidentiality within the NHS against the benefits to the proposed breach of confidentiality. As part of this consideration the Committee generally requests sufficient evidence to demonstrate that the proposed approach yields a significant enough benefit to consider recommending overriding patient confidentiality.

In recommending whether or not support should be provided, the Committee should be provided with sufficient evidence that the requirements and thresholds within the Regulations are met. This includes evidence that:

- The activity fulfils a medical purpose as defined in the NHS Act 2006
- The purpose is not principally for care or treatment
- The purpose is necessary or expedient in the interests of improving patient care or in the public interest
- There is no other reasonably practicable alternative
- The proposed data processing is consistent with the provisions of the Data Protection Act 1998
- There is maximum de-identification and the minimum necessary use of patient information to achieve the stated purposes.

Members advised that while the paper made several analogies to screening programmes, the Committee understands that the Health Check programme is not a screening programme as it had not been accepted as such by the UK National Screening Committee, however, previous Committee

discussions on screening could be applicable here. The key purpose of the Health Check appeared to be to identify risk with treatment usually fed back to GPs in terms of long term interventions.

The initial baseline of the position of the Committee was that there is a practicable alternative to conducting the Health Check that would not require legal support. This was via model 1 where it is delivered by GPs as this would not involve disclosure or breach of confidentiality. It was highlighted that there must be sufficiently persuasive evidence to demonstrate that this approach is not feasible in terms of achieving the stated purposes.

Members noted that while PCTs currently delivered the Health Check, these should not be conflated with local authorities as these are significantly different in terms of structure, responsibility and accountability. Members were aware that changes in legislation would lead to local authorities becoming commissioners of healthcare. What was unclear to members was whether the changes in legislation would provide a legal basis for local authorities to use confidential patient information derived from the clinical record. Members also commented that they thought it likely that where any future support could be applied, that it could not be applied generally to local authorities due to lines of accountability; instead, any support would have to be provided to an individually named local authority.

Members noted that a number of models were proposed, and taking into account the significant step-change in a potential transfer of data to local authorities, were of the view that an equivalently high benefit should be evidenced to justify any potential damage to public trust in the confidentiality of the Health Service, balanced against the public interest in the activity taking place.

Members commented that patients should not receive any surprises caused by information governance practices. Members expressed concern that although they were asked to look at only the information governance concerns potentially preventing GP transfer of data; if this was not the underlying cause then having support in place could not guarantee GP cooperation, and this would impact on the public interest considerations. Since 2001, support under the Regulations has been interpreted to be a permissive power and currently does not require data controllers to disclose information. A number of reasons were cited as to GP non-compliance, however members asked whether any actions had been taken to work with reluctant GPs and queried why this could not take place. Members queried who these alternative providers would be and were informed that this could include pharmacists and other GPs from other practices. Members also queried how alternative providers would be incentivised to reach the ‘hard to reach’ groups.

In reviewing whether model 1 was a feasible option, members queried the extent of non-cooperation, asked if there were any numbers to support this issue and queried the evidence base for the statements around non-cooperation. Attendees commented that some evidence was available. It was highlighted that there was a challenge to reaching full rollout and that currently 55% of PCTs were using mixed models to deliver the service. It was also commented that using only GPs to run the Healthcheck would not capture all relevant patient groups. Local evaluations had indicated that utilising this approach alone would widen health inequalities. Members further queried whether there was a current map of inequalities and if so, had these been prioritised so that it was clear where resources should be appropriately targeted? Responses indicated that no such map had been developed, nor was there the intention to do so.

In response to queries as to whether there were any practicable alternatives, attendees highlighted that there is a policy imperative to reduce health inequalities through delivery of mixed models. It was also confirmed that following stakeholder engagement and discussions with commissioners that it had proved difficult to gain GP participation. Attendees highlighted that the scale of the programme meant that there was a need to exclude the ineligible population otherwise numbers could significantly change and costs increase, and that an economic modelling report could be circulated to support this. Members were informed that some good examples had taken place where utilising an alternative approach had provided evidence of a more significant uptake e.g. placement next to tube stations, using buses as an advertising medium. Members commented that the examples provided seemed to provide evidence of convenience leading to uptake; that if the location was convenient to a patient they would be more likely to take up an offer of a Health Check.

While members raised queries over the potential models it was emphasised that this was not to be taken as criticism of the methodologies. As part of the consideration, members consider the public interest in the outcomes of the proposed models and so aspects of the methodology would come into this consideration. Members suggested that stronger articulation on how the models would achieve the stated aim of reducing health inequalities would strengthen the public interest considerations.

It is a requirement within the NHS Act 2006 in relation to applications made under the Regulations that any approval cannot be inconsistent with the provisions of the Data Protection Act 1998. Members noted an outline of potential measures to ensure compliance with the principles of this Act and welcomed further development of these. This was considered to be highly important as it would involve a transfer of information from the 'NHS family' and therefore it would be important for patients to be made aware of this prior to any such transfer. This is in line with the publicised Bournemouth case where the practice was found to have breached the first Data Protection principle through transferring patient contact details to an independent provider without informing patients in advance. The advisor from the Information Commissioner's Office (ICO) commented that the potential measures should be worked through in further detail in terms of how potential participants would be communicated with in advance of any transfer of information. Reference was also made on the outcome of ICO audits that had looked at standards within local government, therefore assurances would need to be high in this regard. It was advised that for each of the proposed delivery models, a clear articulation of the measures to be taken to ensure suitable fair processing information, tailored to the circumstances of each model, should be worked through. Mr David Evans from the ICO agreed to liaise with the applicants if this was thought helpful and contact details would be provided. Such engagement would be encouraged in terms of identifying what is an appropriate level of assurance. Attendees agreed that the local devolution would provide a freedom in how the Health Check would be implemented, and that they were keen to ensure it was carried out legally and appropriately.

It was noted that the committee were presented with information that included an option where patients that are not eligible could be identified via PDS, however the committee did not review this aspect as there was considered to be fundamental issues to be addressed first. It was also noted that a national cohort management system could be developed, however, as the paper acknowledged that any national solution would take a number of years, members did not consider this aspect further.

A number of other general comments were made that indicated that this activity was considered to be broader than typical 'consent for consent' applications, and seemed to involve issues around broader information sharing. Members also queried that the information held on GP systems on risk factors can change often, and queried how information would be provided to third parties to ensure that it was up to date. Members also queried what would happen to the relevant information should an offer for a Health Check, once data had been transferred to a provider, be not taken up. Members appreciated the attendance and hoped that the discussion was of mutual benefit in aiding the applicants in taking this activity forward appropriately..

2. Code of Practice presentation

Ms Dawn Foster, Head of Information Governance at the Health and Social Care Information Centre, gave a presentation on key points of the HSCIC's new code of practice for confidential information, including the HSCIC's new powers from 1 April 2013 with respect to data collection. A consultation was set to follow in January 2013. Dr Mark Taylor noted that he had already had provided input into the draft code of practice.

3. Protocol on handling data linkage customers

Ms Dawn Foster, Head of Information Governance at the Health and Social Care Information Centre, presented an interim protocol for handling requests from data linkage customers (via the HSCIC's Trusted Data Linkage Service) in the interim to 1 April 2013 when the HSCIC would receive its new

powers under the Health and Social Care Act 2012. The HSCIC sought the Committee's approval of the standard TDLS methodology for creating linked datasets, and proposed that following this, future applications involving access to linked data via the TDLS should only require a supporting letter from the HSCIC to the Committee and not a full explanation of the TDLS methodology in each application. This would, it was hoped, streamline the process for applicant and Committee alike. It was noted that the onus would remain on the applicant to provide evidence of patient engagement, Data Protection Act compliance and other relevant supporting evidence with their application.

4. Public Health England update

Following various discussions that had taken place outside of the meeting schedule, Members carried out a broad discussion on these issues. Members were aware that a number of different functions would be coming together under the governance arrangements of Public Health England (PHE), and many of these functions have continuing approval under the Health Service (Control of Patient Information) Regulations 2002. In terms of the remit of the ECC, it emphasised that it would need to receive assurance that the activities would continue to be carried out in line with the approved purposes as any organisational transfer involves a risk of destabilisation. Members also confirmed that they would support working with relevant persons in order to ensure the current approvals are maintained, and when any proposed changes are made as the organisational change stabilises and would be developed further.

In line with this, members agreed the following, in relation to those transferring functions that have received approval:

1. It would be important for PHE to provide appropriate assurance that the purposes for which approval has been provided for the relevant functions will continue within the agreed details of the application.

2. It is understood that there will be clearly be plans to develop the existing approvals as PHE matures, and this will be dealt with separately from establishing the baseline position.

3. There would need to be an understanding of the governance and organisational processes that will be put into place to ensure that the approval remains as agreed.

4. While the bringing together of various functions is likely to provide opportunities to share and link datasets, unless otherwise stated within the terms of the respective approvals, it is highly likely that this will require amendments to the original applications so as to ensure there is a legal basis for this to take place. Such linkages should not take place unless there is this clearly defined legal basis.

5. A list was provided of potential functions that are intended to transfer into PHE, however the precise future for all were unclear and would require further consideration by PHE. It was identified that PHE should undertake a further review of these applications and clearly identify those where it is definitively known that they will transfer into PHE; agreement should be obtained from the relevant data controllers. There should be a clear understating of what is permitted under each approval and the office could assist on this aspect

6. Members indicated that where any application is unclear as to purposes and scope, particularly for 'old' applications, then in order to bring clarity the application should be brought back to the Committee for review/amendment; to leave the scope open to internal interpretation could potentially be a risk for PHE if it later transpires that the approval has moved beyond its original scope.

7. In terms of the annual review arrangements for those carrying out activities under specific support (Regulation 2 and 3), members indicated they would expect this to continue. Members also noted that, particularly with regard to the cancer registries, they operate to a high level of governance with clearly defined controls, and the expectation would be for this to be

maintained so as to ensure compliance with Regulation 7 (1) (a-e) of the Health Service (Control of Patient Information) Regulations 2002. The importance of organisational compliance with the Data Protection Act 1998 was also highlighted.

8. Usually all existing applications moving under the governance control of a new data controller are required to provide a new application in advance of transfer, providing details of the internal governance arrangements and controls, indicating any changes and ensuring there is a satisfactory Information Governance Toolkit submission or appropriate improvement plan in place. Following discussion with the members and relevant teams, it was agreed that it is not possible for PHE to provide a suitable toolkit submission for 01 April 2013. It has therefore been agreed with the Department of Health IG Delivery team (Ms Marie Greenfield) that the recommended approach is for PHE to work with the IG Delivery Team to develop the toolkit submission/improvement plan, with the intent to provide a report back to the Confidentiality Advisory Group after 6 months to be considered at the October 2013 meeting. The Group would also look to see a report on the developed internal governance arrangements and controls in place and confirmation of the internal

9. At a broader level, Members indicated that they were unclear whether the proposed legal changes would enable local authorities to access the clinical information derived from the clinical record, and would be interested to hear whether a clear legal position has been identified. Members also reviewed the Public Health Factsheets and expressed some disappointment with the content; in particular, the example of using terminations data was surprising to the Committee as this constitutes one of the most sensitive data types. Members also indicated that due regard should be taken of the outcomes of the Caldicott Review when published.

10. It was emphasised that the current Committee (and subsequent Confidentiality Advisory Group) would like to work proactively and positively with Public Health England to ensure a smooth transition and help develop further approvals, and it was strongly emphasised that this opportunity be developed further. Members noted previous helpful conversations with various representatives and indicated they would be willing to continue this aspect.

5. CAG induction

The Committee were advised that advertisements for ten new Confidentiality Advisory Group Members would be published in the Guardian on 12 and 19 December 2012 and would also be published on the web and circulated to stakeholders by email. The Health Research Authority (HRA) was leading the recruitment process and the closing date would be 3 January 2013 with interviews in mid January. These posts were in addition to the six Members (seven including Dr Mark Taylor as Establishing Chair) who had previously been identified to transfer over from the existing Committee to the CAG. The interview panel would be chaired by Dr Taylor, who would also carry out shortlisting. The panel would also include Dr Tricia Cresswell as the new Deputy Chair, the HRA Chief Executive, the HRA Chair or an HRA Non-Executive Director, and a representative of the HRA's human resources function. A discussion was awaited between Dr Taylor and the HRA Chair, Dr Jonathan Montgomery, to clarify the line of accountability from CAG to HRA. Members were concerned at the inclusion of the HRA Chief Executive on the interview panel as this could compromise the CAG's perceived independence, and suggested accountability issues should have been resolved before empanelling the interview panel. The Committee noted the HRA would be holding stakeholder events in January.

The Committee noted that following interviews and presuming successful appointments, the CAG induction day would be 5 February. The final meeting of this Committee would take place on 6 and 7 February and new CAG Members would be in attendance on 6 February as part of their induction. It was suggested that each of the existing Members transferring to CAG should mentor one or more of the new CAG Members. The intention was that CAG should initially function along the same lines as the existing Committee but might subsequently change its processes in line with further outputs of the

Business Improvement Programme, which might include an increase in proportionate review applications and a corresponding decrease in applications considered by the full Committee. Dr Mark Taylor and Dr Alan Doyle, NIGB Director, were jointly producing draft terms of reference for CAG based on the existing NIGB and ECC terms of reference.

6. Business Improvement Programme

Mr Mathew Fry, NIGB Operations Manager, reported that the Business Improvement Programme had delivered as planned to date. Further work would be built on by the HRA-led transition project group and would be led operationally by the HRA's new Section 251 function lead once appointed, but the aim was to preserve the legacy of good work achieved to date, including principles for decision making. Areas of further work that had been identified included a review of policies and precedents to help support new Members and articulate historic decisions of the existing Committee.

Dr Alan Doyle, NIGB Director, advised the Committee that the NHS Commissioning Board planned to establish an overarching information coordination group with multi-agency membership. This group would be supported by several sub groups including an information governance group, which would inherit work currently being carried out by the multi-agency Information Governance Professional Leadership Group. It was envisaged that the HRA would have a director-level representative on the new information governance group.

7. Any other business

The Chair expressed his thanks to the Office staff and Members for all their hard work and support, and congratulated Members who were transferring to CAG. He clarified that although he would complete all areas of work already agreed, any new requests for Chair's action should with immediate effect be directed to Dr Mark Taylor who would serve as Acting Chair prior to taking on the substantive Chair role from 1 January 2013.

8. Upcoming meeting dates

6 and 7 February 2013