Information Governance

National Information Governance Board for Health and Social Care

Annual Report 2009

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Rt. Hon. Andy Burnham MP
Secretary of State for Health
Department of Health
Richmond House
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01 November 2009

Dear Secretary of State,

I am pleased to enclose a copy of our annual report for 2008/09.

The National Information Governance Board for Health and Social Care (NIGB) became a statutory body in November 2008. Our role is to support improvements to information governance practice, to monitor information governance trends in the NHS and Adult Social Care and to administer applications to use section 251 of the NHS Act 2006 which is important in supporting legal medical research and other important uses of information in the NHS. The NIGB meets every two months and reports annually to you.

We believe that good information governance not only helps drive forward improvements in quality in both health and social care but also empowers the public to be confident in contributing to their own care. In this report we explain what information governance is, the role and remit of the Board, what we have achieved in our first year as a statutory body and information about our board members. Any references we make to the NHS or to social care do, of course, include those from the independent or third sectors delivering services under contract for the NHS or local authority social care teams.

Last year I wrote of the significant and welcome attention being given to information governance across government and the greater recognition of the value of safe, secure and confidential data sharing. It is therefore disappointing to read that the Information Commissioner continues to have to issue warnings to some NHS organisations which have breached the Data Protection Act 1998. We are not aware of a similar number of warnings being issued to social care. This may be due to differences in performance or just differences in reporting and is a matter which we hope to look into.

Over the past 12 months we have provided your predecessor with advice on information governance matters around the NHS Constitution and the Coroners and Justice Bill, and we hope this was helpful. In both cases we were concerned that a commitment to keep information confidential was being seen as a replacement for consent. Our position is that consent is a requirement for confidentiality.

continued overleaf...

National Information Governance Board for Health and Social Care

We have also, at his request, advised the Chief Medical Officer on information governance during the swine flu pandemic.

In October we launched the Social Care Record Guarantee for England. We hope that this guarantee will not only benefit service users and staff but, together with the NHS Care Record Guarantee for England, will form the basis for safe, legal and effective information sharing between health and social care. The NHS Care Record Guarantee for England, which we review annually to ensure it continues to reflect the law and best practice, was first published in 2005 since when over 220,000 copies have been distributed.

The NIGB promotes safe, secure and confidential data sharing with consent. We support good clinical and epidemiological research in improving healthcare delivery and outcomes for the population as a whole. We have been working to find a legal solution to improving patients' timely access to research. In support of this we have met with senior officials at the Department of Health and researchers to discuss possible options. We continue to seek a solution which respects patient consent and encourages patient and public engagement in research.

We heard from patients who were having difficulties in getting errors corrected in their medical records or having their comments added. We felt this represented a broader issue and have produced guidance for the public and professionals. Our guidance underwent public consultation over the summer which was very supportive and we will publish it later in the year.

In January the NIGB took over the statutory functions of the Patient Information Advisory Group (PIAG). Our Ethics and Confidentiality Committee (ECC) now carries out the important role of supporting research and other NHS activities, ensuring that the use of identifiable data is legal. We are grateful to the members of PIAG who agreed to join the ECC to ensure continuity and a smooth transition, especially to Professor Dame Joan Higgins who chaired PIAG since it was established in 2001 and chairs our Ethics and Confidentiality Committee until December , for her support and leadership.

As a board we have dealt with some challenging issues over the past year and again I would like to express my thanks to all the members of the Board for their positive approach and also to our advisors who have supported us in this.

I hope that we will continue to be a constructive contributor to improvements in information governance in health and social care.

Yours sincerely

Harry Cayton
Chair

National Information Governance Board for Health and Social Care

"We also recognise that much of the NHS and social care are still reliant on paper records with their inherently different information governance challenges."

The National Information Governance Board for Health and Social Care (NIGB)

What is information governance?

The term information governance is used to describe the structures, policies and practices which are used to ensure the confidentiality and security of the records of patients and service users. Correctly developed and implemented it enables the appropriate and ethical use of information for the benefit of individuals and the public good.

About the National Information Governance Board for Health and Social Care

Why is there a National Information Governance Board for Health and Social Care?

A review of information governance in the Department of Health and the wider NHS (available at ***http://www.nigb.nhs.uk/about/publications/igreview.pdf***) carried out in 2005 commented on the absence of a single coordinating body which, in the case of disagreements about interpretation of best practice or in the pursuit of advice, could be a single authoritative source of advice or arbitration. The review recommended that a National Information Governance Board covering both health and social care should be established and this recommendation was accepted by Ministers.

Having operated in 'shadow form' since October 2007, the Health and Social Care Act 2008 made the NIGB a statutory body (an Advisory Non Departmental Public Body sponsored by the Department of Health) in November 2008.

The 'shadow' NIGB had already taken over the functions of the Care Record Development Board and on 1 January 2009 the statutory NIGB took over the functions of the existing statutory body, the Patient Information Advisory Group (PIAG).

What the NIGB is in place to do

Overall the role of the NIGB is to support improvements to information governance practice in health and social care. Its full terms of reference are to:

- Provide leadership and promote consistent standards for information governance across health and social care, to enable ethical, legal and policy issues to be appropriately dealt with;
- Monitor information governance trends and issues through analysis of annual information governance returns from all bodies using or holding NHS or social care information;
- Arbitrate on the interpretation and application of information governance policy and give advice;
- Have oversight of and advise on the confidentiality management and access control frameworks implemented through the National Programme for IT;
- Own and review the NHS Care Record Guarantee for England annually;
- Advise the Secretary of State on any matters of information governance that should be brought to their attention and to produce an annual report to the Secretary of State;
- Deal with other such matters as required by the Secretary of State and other appropriate bodies; and
- Work with appropriate bodies, including those in the home countries, on issues within its remit.

> ***I have found the ECC team so helpful and cooperative and the whole process seems streamlined and easy to follow. This is my first experience of making an application to the ECC and I have to say it has been very positive.***
>
> *Senior Research Nurse*

The NIGB has statutory powers under the Health and Social Care Act 2008 which support it in fulfilling its terms of reference. These are:

- All information obtained or created as part of the delivery of NHS funded healthcare or adult social care services delivered by local authorities, including services provided under contract to the NHS and local authorities, comes under the remit of the NIGB. This is irrespective of whether the information identifies patients or service users or is anonymised;
- The Board has the power to issue advice to any individual or organisation using this information irrespective of whether advice has been requested. NHS bodies and local authorities have a statutory responsibility to 'give regard' to advice from the NIGB and to respond if the NIGB seeks clarification on how its advice has been used;
- The Board also has a responsibility to assure itself that organisations have regularly reviewed their information governance practices and if they have determined that these are fit for purpose; and
- To provide advice to the Secretary of State for Health on the use of powers under section 251 of the NHS Act 2006 (see page 16).

Full details of the NIGB legislation in the Health and Social Care Act 2008 are available at ***http://www.opsi.gov.uk/acts/acts2008/ukpga_20080014_en_1***. The NIGB details are in clauses 157-158.

Why include both Health and Adult Social Care?

The boundaries between health and social care are blurring, especially from the perspective of service users, and this means that information often has to be shared between these two services. Patients and service users expect the rules that govern how their information is used and shared to be the same in both health and social care, but historically this has not been the case.

Whilst the remit of the NIGB covers all health information it only covers adult social care information. Responsibility for children's social care policy, and consequently the governance of children's social care information, rests with the Department for Children, Schools and Families (DCSF). The NIGB has a good working relationship with the DCSF and they are represented at our board meetings.

How does the NIGB fulfil its remit?

- **Leadership -** Stakeholder organisations represented at the NIGB (page 25) includes both health and social care organisations and, with and through these, the NIGB provides leadership and promotes consistent standards for information governance across both health and social care.

- **Giving patients, service users and the public a voice -** More than half of the members of the NIGB are members of the public, appointed by the independent Appointments Commission after a public recruitment campaign. The public members ensure that the perspective of patients, service users and the public is taken into account when the Board discusses or provides advice or guidance on governance matters.

- **Advice to care professionals -** The NIGB provides advice on the interpretation of policies, guidelines and legislation relating to information governance. There are many policies, procedures, legislation and professional guidelines which relate to the use and sharing of patient and service user information. Whilst the general principles are consistent there can be differences in the detail which can make it difficult for those providing care to be sure that they are acting appropriately. NHS and social care organisations have individuals, called Caldicott Guardians[1], in place to support staff in ensuring that information is handled appropriately and most will also have information governance boards or committees. The NIGB provides a forum where these people can seek guidance on the interpretation of legislation, policies and guidelines in situations where they feel unable to decide on the correct action.

- **Advice to patients, service users and the public -** The NIGB owns and reviews the NHS Care Record Guarantee for England (available at ***http://www.nigb.nhs.uk/guarantee/2009-NHS-CRG.pdf***). This was first published in 2005 and sets out for patients how their information should be used so that their rights are protected and their health and wellbeing promoted. In October we launched an equivalent guarantee for social care records (available at ***www.nigb.nhs.uk/social-care***) and the NIGB also owns this. Not complying with the NHS Care Record Guarantee or the Social Care Record Guarantee could be used as the basis of a complaint and how people can complain about the use of their information is explained in the Guarantees. A number of people write to the NIGB seeking advice. Wherever we can we provide them with advice, but the NIGB is not able to investigate individual patient or service users complaints.

- **Providing a legal basis for the use of information in medical research and other NHS activities -** Section 251 of the NHS Act 2006 provides powers for the Secretary of State for Health to allow the common law duty of confidentiality to be set aside in specific circumstances so that information which identifies patients can be used for NHS activities and medical research without patients' consent. The NIGB Ethics and Confidentiality Committee advises on the use of this law and administers applications to use it.

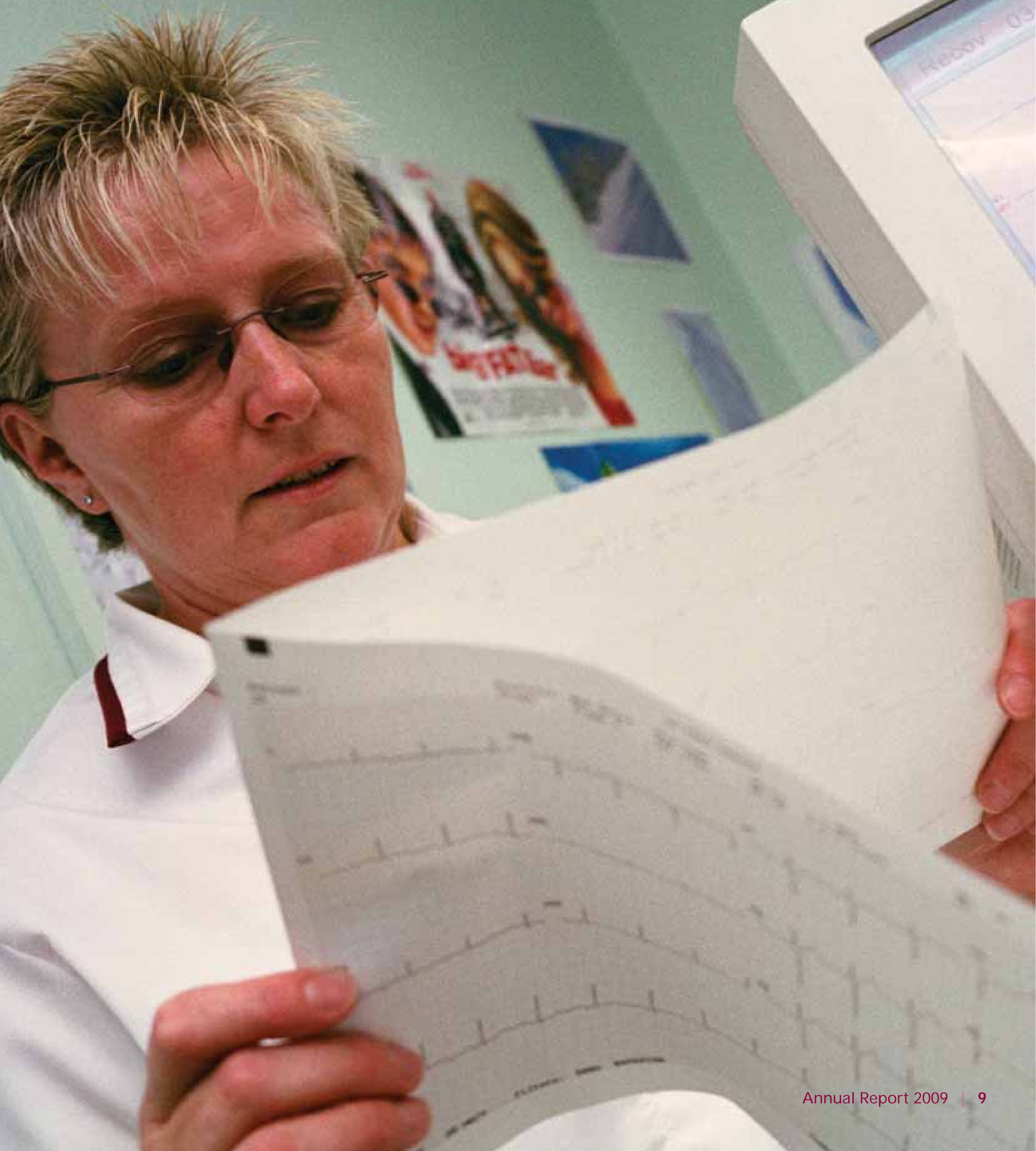
- **Monitoring and oversight -** NHS organisations are required to assess their information governance performance annually using the Information Governance Toolkit (available at ***https://www.igt.connectingforhealth.nhs.uk/***). The NIGB oversees the content of the toolkit and uses the annual returns to monitor information governance trends and issues. The NIGB is supporting work to increase the use of the toolkit within social care. New IT systems are being implemented in all NHS organisations in England either by individual organisations or through the NHS IT programme. The NIGB maintains an oversight, provides advice and guidance, and reviews access control frameworks.

- **Links with other countries -** The devolution of government has led to differences in the way that healthcare and social care are delivered across the UK. The NIGB works closely with similar boards in Wales and Scotland.

- **Ensuring a consistent approach -** The Board has agreed a set of principles that it uses to promote a consistent approach to its decision making and the provision of advice and guidance. These are shown in Annexe 1 and are also available on our website at ***http://www.nigb.nhs.uk/about/meetings/NIGBprinciples.pdf***.

[1] A Caldicott Guardian is a senior person responsible for protecting the confidentiality of patient and service user information and enabling appropriate information sharing. The Guardian plays a key role in ensuring that the NHS, Councils with Social Services responsibilities and partner organisations satisfy the highest practicable standards for handling patient identifiable information.

"The NIGB provides advice on the interpretation of policies, guidelines and legislation relating to information governance."



Chair's Report

Information sharing is becoming more important for high quality care, easier through multidisciplinary working and more risky through electronic communication. These developments bring challenges about how to share information in ways which benefit patients, service users and professionals whilst adhering to good information governance principles and the law. In this report I set out what we have done as a board over the past year both to support the value of data sharing for quality and also to uphold patients' rights about the use of their information.

The National Information Governance Board for Health and Social Care became a statutory body in November 2008 and its remit, which is set out in sections 157 and 158 of the Health and Social Care Act 2008 (***http://www.opsi.gov.uk/acts/acts2008/ukpga_20080014_en_13#pt5-pb5-l1g157***) is both wide reaching and challenging.

Whilst media attention inevitably focuses on electronic records, the NHS IT programme and the introduction of joint health and social care assessments including the Electronic Single Assessment Process and the Common Assessment Framework we also recognise that much of the NHS and social care are still reliant on paper records with their inherently different information governance challenges.

In July we carried out the annual review of the NHS Care Record Guarantee for England. We publish the Guarantee and are responsible for upholding it and reviewing it annually to ensure it reflects any changes in the law or working practices. The Guarantee was originally launched by Department of Health Ministers in 2005 and sets out for patients and the public how their information is used by the NHS and what control they can have over this. Since its launch over 225,000 copies of the Guarantee have been distributed.

We continue to uphold the Guarantee by promoting the balance between public and personal good and by ensuring that it remains focused on the interests of patients and the public. It is reassuring to find that, as was the case with previous annual reviews, there were no requests to modify the principles behind any of the 12 commitments. The only changes necessary were to improve clarity and understanding.

In October we launched the Social Care Record Guarantee for England, a new publication which was produced by the members of the Electronic Social Care Record Implementation Board and mirrors the NHS Care Record Guarantee.

The launch of the Social Care Record Guarantee is significant for three reasons. Firstly, it is of clear benefit to social care service users and staff. Secondly, as the boundaries between health and social care are blurring the Social Care Record Guarantee and the NHS Care Record Guarantee together form an ideal basis for developing appropriate, secure and legal information sharing between social care and health. Thirdly, it is a good example of government departments working together to ensure effective information governance. The remit of the NIGB covers the policy areas of the Department of Health - health information and adult social care information. The Department for Children, Schools and Families (DCSF) has responsibility for children's social care information policy and they have agreed to support the Social Care Record Guarantee as a guarantee for both children's and adult social care records. I am grateful to DCSF for their support. The secure sharing of information about children is essential for their wellbeing and to identify possible risks to a child at an early stage.

In my last report I indicated that we welcomed the commitments to confidentiality and patient access to their records included in the NHS Constitution. However, we had also expressed our concerns to the Secretary of State for Health about the proposal to allow health or research professionals outside the care team to use care records to identify patients who were suitable to participate in approved clinical trials without the informed consent of the patient. Other bodies raised similar concerns and I am pleased that the NHS Constitution Handbook was modified. All the evidence suggests that the public are supportive of clinical research and willing to be involved but that they think consent and confidentiality are essential requirements. So we have continued to work with the Department of Health on a way forward within the existing legal framework.

Balancing the public and personal interests in the use of identifiable health information for research is difficult. Where consent cannot be sought the law (section 251 of the NHS Act 2006) allows such use in defined circumstances. We have continued to advise on the use of identifiable data in the public interest through our roles in advising the Secretary of State on the use of these powers and administering applications to use it. More detail of our work in this area is given on page 16.

The Coroners and Justice Bill, as first issued, contained clauses allowing information sharing orders to be set up. We supported Department of Health Ministers in pressing for health and social care records to be excluded from the information sharing orders. Other stakeholder bodies and the media were also supportive of this position and information sharing orders were removed from the Bill. This was a welcome response from the Government to public concern about privacy.

It is disappointing that confidentiality and consent are sometimes confused so that a commitment to keep information confidential is seen as replacing the need to seek consent. The NIGB is clear that consent is a precursor to confidentiality - one cannot keep information confidential unless one has permission to know it in the first place. Looking at identifiable private information without consent is in itself a breach of confidentiality. Both the NHS Care Record Guarantee and the Social Care Record Guarantee make clear commitments to seek consent and to keep information confidential.

One of the NIGB's roles is to review the Information Governance Toolkit returns annually and we did this in July. The toolkit is a self-assessment tool which enables organisations to assess their performance against key information governance criteria or themes. Whilst its use is mandatory in the NHS, this is not the case in social care. Some social care organisations have completed the toolkit as part of their commitment to improving information governance standards within their organisations and also as a requirement to securely share service user information with the NHS using the NHS computer network. This is an area that we will watch with interest.

The toolkit consists of a series of questions (NHS acute trusts, for example, have to answer 62 questions) grouped into 6 themes:

- Information Governance Management;
- Confidentiality and Data Protection Assurance;
- Information Security Assurance;
- Clinical Information Assurance;
- Secondary Use Assurance; and
- Corporate Information Assurance.

Chair's Report *continued...*

Organisations score themselves against each question from level zero to three based on the evidence required in the toolkit to achieve each level. The result is that organisations are either 'red', 'amber' or 'green'.

The trends indicated a general improvement for each theme since our previous review in 2008. The scores for corporate information assurance across all types of NHS Trust has not yet reached the same level as the other themes.

Whilst we were, to a degree, reassured to find that no individual Trusts were now scoring in the 'red' rating band, there remained a small number still in the 'amber' band. Although this is an improvement on previous years we would clearly like to see all organisations in the 'green' band. However, an organisation can still attain a green status whilst failing some of the requirements of the Toolkit and we will be pressing the Department of Health to continue to raise the score needed to achieve 'green' status so that this is no longer possible.

Useful though the toolkit is as a self-assessment tool, it should not be taken as providing assurance of the standard of information governance in an organisation. Whilst the toolkit return has to be signed off by a chief executive or equivalent, it is subjective and so inevitable that organisations that score themselves rigorously and therefore achieve a lower score than others may in fact be performing better than those whose scoring is generous.

Our doubts about the reliability of the toolkit as a reporting mechanism are reinforced by the fact that the Information Commissioner continues to have to issue warnings to NHS organisations which have breached the Data Protection Act 1998. Whilst this applies only to a small number of organisations, the theme seems to be exactly the same as it was last year: all the examples of data loss which have come to our attention are the result of human error or foolishness. Last year we said that the lesson from this was that whilst we could and should develop information governance systems and procedures that create a high level of security, nevertheless human error or intent would always create a risk. Data management systems, whether paper or electronic, could assist good practice but not replace it and should ideally be enforced by appropriate training. This remains the case and we are very pleased to see that some compulsory information governance training for all NHS staff has been introduced.

The Department of Health is to be commended in developing the Information Governance Toolkit and organisations for using it. We recommend however that further steps are taken to improve the consistency in the way the questions are understood and responded to, and also that there should be local independent assurance of the validity of scores.

Overall we found analysing the toolkit returns in order to understand both local and national pictures to be problematic. We will be working with the Department of Health's Digital and Health Information Policy Team and the Care Quality Commission, who also analyse the data, to work out how we get the most appropriate information to consider, and also how the information might best be made available to patients and the public.

We are clear that employers, professional bodies and the Royal Colleges must all accept that they have a key role to play in promoting good information governance and ensuring that this is included in the training they provide.

A review of the information governance content of clinical training by our NHS Lead has shown that whilst basic training includes elements of record keeping and the ethics of confidentiality, there appears to be little or no training for clinicians on the wider information governance requirements and in particular the impact of the introduction of electronic records. We have approached a number of Royal Colleges and professional bodies asking them to include the NHS Care Record Guarantee and its implications in their future curricula for clinicians, practice managers and record managers. All of the bodies who responded agreed to include debate on the wider information governance knowledge needs at their next curriculum review meetings.

Our NHS Lead and our Social Care Lead have also developed a master class on information sharing which has been piloted with health and social care students at Teeside University. We will continue to support the development of information governance training with all specialities of clinical students and hope to extend this to social care students.

For the NIGB to be effective there have to be good lines of communication between it and front line social care and NHS staff, and our Representative Members and Corresponding Advisors play a key role in this. Also our NHS Lead and our Social Care Lead have visited Information Governance Leads groups across England to explain the more detailed work of the NIGB, the roles of the NHS and Social Care Lead and to seek comments on, and contributions to, the work of the NIGB.

We have taken every opportunity to promote the value of good information governance and to share the development of information governance practice, attending, participating and speaking at workshops and conferences when invited. A later section of this report shows the events we have attended.

Some of the other bodies working in information governance have questioned their role now that the NIGB is a statutory body. We are clear that we cannot operate alone. In promoting consistent standards in information governance the NIGB needs to work with many organisations and bodies, and we recognise that there are more of these than can practically be members of the NIGB.

However, we do aim to have effective and open working relationships with all organisations which are promoting or operating good information governance practice in health and/or social care. To support this we have introduced Statements of Collaborative Working. These are high level agreements to formalise the working relationship between an organisation or body and the NIGB. They acknowledge a mutual interest in fostering and promoting good information governance practice. Of course we recognise that there may be issues on which the NIGB and the organisation do not agree and we accept the challenge and debate as part of the collaboration. To date we have Statements in place with the Association of Medical Research Charities, the UK Council of Caldicott Guardians and the patient and user consortium, National Voices.

Over the next 12 months we hope to build on this and will also work with our Representative Members and Corresponding Advisors to ensure that we are fully aware of the information governance issues and concerns of those they represent and that we support the resolution of these.

We are pleased that the Board's advice continues to be sought and that the NIGB Office is dealing with a steady stream of enquiries by email, post and phone.

As a board we have found our work over the past year both demanding and fulfilling and we look forward to the next 12 months. We hope that we have gained a reputation for providing pragmatic, practical solutions to the dilemmas which are brought to us whilst continuing to be strong in upholding the law, patients' and service users' rights and the Care Record Guarantees.

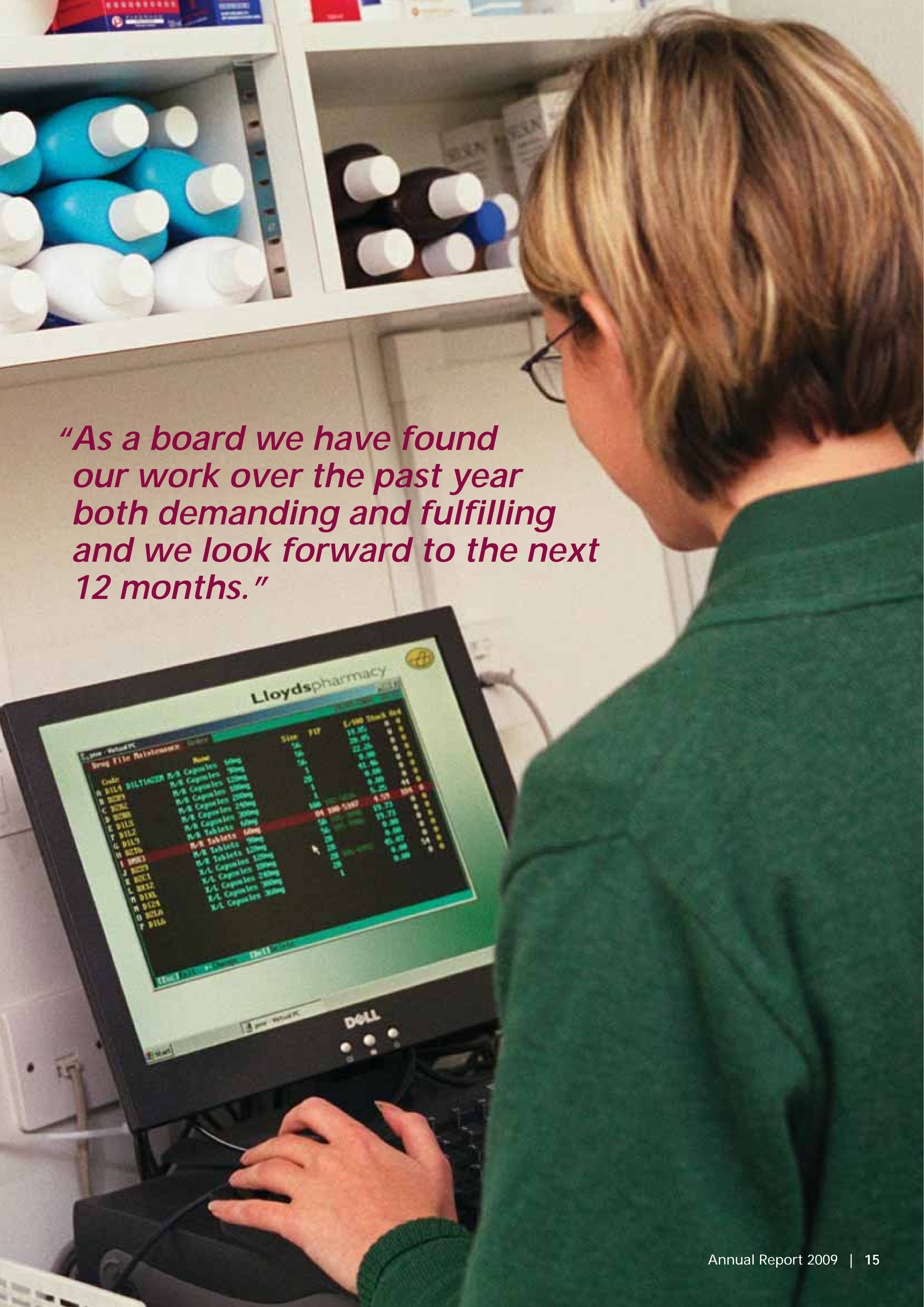
On 1 January 2009 we took over the responsibilities of the Patient Information Advisory Group (PIAG). To ensure there was continuity we invited the members of PIAG to join our Ethics and Confidentiality Committee (ECC) which administers the Board's responsibilities under section 251 of the NHS Act 2006. We are pleased that the majority of members agreed. The transfer of functions has been very smooth and we are grateful to the Chair and members of the ECC for this.

As well as publicly appointed members and representative members we also have corresponding advisors and we are grateful to them for their support, for the time they take to review board papers and for their helpful comments and probing questions.

Over half the members of the NIGB are members of the public appointed to the Board by the Appointments Commission on behalf of the Secretary of State for Health. The appointments are for a variety of fixed periods and in mid 2010 a new recruitment campaign will start. I would encourage anyone who has taken the time to read this report and has an interest in the role of the NIGB to consider applying to be a member. The details will be on our website and the Appointment Commission's website (***www.appointments.org.uk***) around May to July 2010.

I cannot close my report without mention of our board member and Chair of our Ethics and Confidentiality Committee, Professor Dame Joan Higgins. Professor Higgins chaired the PIAG from its inception in 2001 until the NIGB took over its functions in January 2009, and then, despite an already significant public sector workload, agreed to support the transition of the functions to the NIGB for 12 months which ends in December. The transfer of the PIAG functions to the NIGB has been achieved. The ECC is working well and, like PIAG before it, is facilitating research and other valuable data uses, whilst promoting patient confidentiality. Under Professor Higgins leadership PIAG not only showed good judgement in the use of section 251 powers but was also instrumental in the development of good practice in the use of patient information for secondary purposes. All of us who work with and around patient information owe her a debt of gratitude for her dedication, incisiveness and the sound judgement that she has brought to these complex issues.

Patients, service users, members of the public or professionals, if they have any comments on this report or on our work in general, are welcome to contact us via our postal or our email address, both of which are shown at the beginning of this document.



"As a board we have found our work over the past year both demanding and fulfilling and we look forward to the next 12 months."

Providing a legal basis for the use of information in medical research and other NHS activities

Introduction

Section 251 of the NHS Act 2006 (previously section 60 of the Health and Social Care Act 2001) provides powers for the Secretary of State for Health to allow the common law duty of confidentiality to be set aside in specific circumstances so that information which identifies patients can be used for NHS activities and medical research without patients' consent.

The NIGB took over the administration of section 251 from the Patient Information Advisory Group (PIAG) on 1 January 2009 and has delegated this responsibility to its Ethics and Confidentiality Committee (ECC). Whilst the other responsibilities of the NIGB relate to England only, its responsibilities under section 251 relate to both England and Wales.

Members of the ECC carefully consider each application made and make a judgement on whether the benefits of the NHS activity or proposed research are significant enough to set aside the common law duty of confidentiality in favour of public interest. Applicants need to demonstrate that seeking consent, or using anonymised or pseudonymised data, is not practicable or possible for their study. Members also look for effective patient and service user involvement in the study and an exit strategy from the use of section 251 - for example that steps will be taken to seek consent in future.

The use of section 251 is an important function and many factors need to be taken into account when considering applications. The skills and experience needed to assess applications take some time to build up. To ensure continuity members of PIAG were invited to join the Ethics and Confidentiality Committee and most, including the Chair, agreed. To ensure appropriate governance arrangements, the Chair of the ECC is a full member of the NIGB and two other members of the NIGB are ECC members.

Biographies of ECC members are on page 28.

Applications to use section 251

Applications to use section 251 come from a range of organisations, including the Department of Health, NHS organisations and research institutions. In the ten months since the NIGB has been responsible for the administration of section 251 to the publication of this report it has received 72 applications.

Applications approved	42
Section 251 not required	8
Declined	20
Pending	1
Appeal pending	1
Total	**72**

Further details of section 251 applications can be found at Annexe 3, and the register of all approved applications is at ***http://www.nigb.nhs.uk/ecc /register-1***. During the first half of 2009, the number of applications has increased. This may be due to an increase in the general awareness of the need for section 251 support or it may be connected with the introduction of the Integrated Research Application System (IRAS) through which researchers apply for the full range of approvals for their research projects and which reminds them to consider the need to use section 251.

The workload of the ECC will continue to increase because we have now agreed to consider applications to use patient identifiable information without consent:

- held on the Human Fertilisation and Embryology Authority (HFEA) Register;
- held by NHS Connecting for Health on the Demographics Batching Service (DBS); and
- where applications for information from the Central Register are made via the NHS Information Centre for Health and Social Care.

In most circumstances local internal clinical audits do not require section 251 support for the use of patient identifiable information as long as the audit fulfils certain criteria. However, if third party organisations are used to conduct clinical audit and consent is not feasible then section 251 support is needed.

National clinical audits and national planning to deliver NHS services should use de-identified data. Where identifiable data is needed the ECC expect reasonable attempts to be made to seek consent and involve patients and service users. If this is not practicable then section 251 support must be sought.

Additionally, some of this national work is being led by government bodies which submit applications to the ECC at a very late stage. Early consultation with us can only bring benefits as appropriate approval and advice can be provided as the work develops.

There have been an increasing number of applications from researchers who wish to set up databases or disease registers with no clear description of how they will be used. One of the recommendations of *The Royal Liverpool Children's Inquiry Report* (the Alder Hey Report), in 2001, was that tissue samples or patient data should only be collected with specific research questions in mind and with consent. When the ECC has considered such applications it has, in line with the recommendation, only approved them where a clear purpose for the database has been articulated and usually with the expectation that consent will then be obtained where there is a need to retain identifiers.

The ECC has also noticed a growth in the number of 'advisory committees' which are being established to govern access to these databases. There is concern about the duplication of activity, the legal basis for the work of these committees and recruitment of members.

In addition to reviewing section 251 applications, at the meeting of the ECC in July, it also reviewed the draft '*NHS Code of Practice on Confidentiality - Supplementary Guidance; when might disclosure of confidential patient information without consent be justified in the public interest*' and the Wellcome Trust Report '*Towards Consensus for Best Practice - Use of patient records from general practice for research*'.

"Our team found that your approach in guiding us and in processing our applications to be highly professional and very sensitive and generous."

Section 251 applicant

Database Monitoring Subgroup

During 2005, a review of information governance in the Department of Health and the wider NHS, was carried out on behalf of the NHS IT Programme Board (the review report is available at ***http://www.nigb.nhs.uk/about/publications/igreview.pdf***). As a result of the review the Security and Confidentiality Advisory Group (SCAG) was closed and its functions were transferred to PIAG. PIAG established the Database Monitoring Subgroup (DMsG) to carry out these functions and also some of the functions of the Office of National Statistics' Advisory Group for Medical Research, which closed following the transfer of the NHS Central Register to the NHS Information Centre for Health and Social Care.

The DMsG is now a subgroup of the NIGB Ethics and Confidentiality Committee. The Group considers applications for extracts containing sensitive but not directly identifiable data from the Hospital Episode Statistics (HES) database. HES is a national database which records all hospital admissions and care provided by NHS hospitals and for NHS hospital patients treated in other settings. It does not contain people's names and addresses, but coded details of the care they received. Sensitive data items are those which the DMsG considers, should they be disclosed, may cause greater harm or distress to the patient. The DMsG recommends, where necessary, additional safeguards given the sensitive nature of the data and ensures that a combination of, or linked data items, do not result in identifying an individual.

The DMsG also reviews applications made via the Medical Research Information Service (MRIS) for access to records on the Central Register. The Central Register is a computerised record of every patient registered with a general practitioner in England, Wales and the Isle of Man. The DMsG checks that where consent has been sought from research cohorts, that the consent is valid for the purpose of the study. A summary of applications considered by the DMsG is opposite. Further details are at Annexe 4.

HES Applications

Approved	15
Withdrawn	1
Pending	1
Total	**17**

Central Register Applications

Approved	18
Referred to Ethics and Confidentiality Committee	1
Total	**19**

Appeals and Complaints Procedure

Whilst PIAG received only two complaints during the eight years that it was established the relationship between the ECC and the NIGB has allowed a formal appeals and complaints procedure to be put in place. Should applicants disagree with either a decision made by the ECC or DMsG or are unhappy about the way their application was processed by the NIGB Office, they can make a complaint or appeal. The full appeals and complaints procedure is available on the NIGB website at ***www.nigb.nhs.uk/ecc/applications-and-guidance/AppealsComplain.pdf***.

"The NIGB promotes safe, secure and confidential data sharing with consent."

Our work in 2008/09

In the meetings since the last annual report in 2008 and the time this report went to press we have:

Provided advice and guidance on:

General Information Governance Matters

- NHS Connecting for Health User Self Service Fallback Smartcard process;
- The Department of Health/Connecting for Health Research Capability Programme;
- The General Practice Extraction Service;
- Piloting patient access to electronic records;
- The Information Centre Information Governance Framework and Compliance Unit;
- The information governance implications of the Coroners and Justice Bill;
- Consent for diagnostic tests;
- The launch of the Social Care Record Guarantee;
- Deleting Summary Care Records;
- Parental controls on information sharing for children;
- NHS Information Governance Toolkit returns 2008/09;
- The use of third parties to support collaborative care;
- The Hampshire Health Record;
- Access to clinical information by social workers using the Common Assessment Framework;
- The roll-out of the Summary Care Record by NHS Connecting for Health; and
- Access to demographic information for purposes other than care.

Applications to use patient information

- The Ethics and Confidentiality Committee received 72 applications to use section 251 of the NHS Act 2006 (see page 16) and declined 20; and
- The Database Monitoring Subgroup received 36 applications to access sensitive information or to validate consent and approved 33.

Accepted:

- Social care access to the Personal Demographic Service (part of the NHS Care Records Service);
- NIGB Communications strategy;
- The 2009 review of the NHS Care Record Guarantee for England; and
- Guidance from an NIGB Working Group on the amendment of medical and social care records following a request from people receiving care.

Considered:

- The Government response to the Thomas Walport Review of data sharing;
- Information governance and social work conduct and practice;
- A report to the Board on Patient Privacy, UK Law and European Standards from Dr Paul Thornton;
- A Care Quality Commission report on information governance practices; and
- The Wellcome Trust Report "Towards Consensus for Best Practice - Use of patient records from general practice for research".

Outside meetings we have:

Provided advice and guidance to the Chief Medical Officer on information governance during the swine flu pandemic.

The NIGB Chair has spoken about information governance and the role of the NIGB at:

- onCore UK Workshop on Ethics and Governance in Cancer Biobanking;
- Connecting for Health - National Clinical Leads Forum;
- Lancet Health of the Nation Summit;
- EnCoRe User Advisory Group Meeting;
- UK Council of Caldicott Guardians conference;
- Working Party on NHS IT;
- Foundation Trust Network Company Secretaries Network;
- PRIMIS+ annual conference;
- International Society for Quality in Health Care Conference.

NIGB Office staff have given presentations on information governance to:

- Birmingham Anglia Integrated Clinical Environment Conference for Radiology and Pathology;
- Teesside University Information Governance Masterclass for Health and Social Care Students;
- A National Conference for Information Governance Leads organised by 'IG4U'.

Provided evidence to:

- The Department of Health consultation on the Common Assessment Framework;
- The Department of Health consultation on new Health Protection Regulations related to Notification, Part 2(a) orders and Local Authority powers;
- The UK Research Integrity Office consultation on their Code of Practice for Research;
- The British Standards Institute consultation on standard BS 10012: Specification for the management of personal information in compliance with the Data Protection Act 1998;
- The Nuffield Council on Bioethics Consultation on Medical profiling and online medicine;
- The Department for Children, Schools and Families consultation on Proposed Harmonised Data Standards and Definitions for the Children's and Young People's and Local Government Workforce Consultation;
- The NHS Connecting for Health consultation on Public, Patients and others views on additional uses of patient data;
- The General Medical Council consultation on supplementary guidance on *Good practice in research* and *Consent to research*;
- The General Medical Council consultation on supplementary guidance on *Making and using visual and audio recordings of patients*;
- Care Quality Commission Consultation on the Guidance about compliance with the Health and Social Care Act 2008 (Registration Requirements) Regulations 2009.

> ***Without the help and guidance of the NIGB I think that I would still be struggling to protect my medical records from inappropriate access. Well done the NIGB!***
>
> *A member of the public*

The NIGB Members

The NIGB was established to give assurance to service users and the public that their information is being shared and used appropriately. To emphasise this commitment to the public, more than half of the members of the NIGB who attend board meetings are members of the public who have responded to a public recruitment campaign and been appointed by the Appointments Commission. The remaining members represent organisations which are stakeholders in information governance and have been invited to be represented on the Board.

Chair

Harry Cayton

Harry Cayton OBE was appointed Chair of the statutory NIGB by the Appointments Commission in 2008. He has been Chief Executive of the Council for Healthcare Regulatory Excellence (CHRE) since August 2007. He was formerly National Director for Patients and the Public at the Department of Health. From 1992 to 2003 he was chief executive of the Alzheimer's Society and from 1981-1992 Director of the National Deaf Children's Society. Harry was Chair of the Care Record Development Board from 2004 until it closed in summer 2007 and also chaired a Ministerial Taskforce on the Summary Care Record in 2006. Harry is an advisor to both Macmillan Cancer Support and The Health Foundation and is a trustee of both Comic Relief and the Friends of Alzheimer's Disease International.

Public Members

Edward Briffa

Edward Briffa is Head of BMJ Learning at BMJ Group and has a background in online medical education, online broadcasting and TV production. This included working for the BBC for many years, as a science editor, award winning TV producer and he also led the launch of BBC Online and Interactive services. He is also an external member of the Council of the Open University.

Rodney Brooke

Sir Rodney Brooke CBE DL is Chair of the Quality Assurance Agency for Higher Education and a member of the General Medical Council. He was Chair of the General Social Care Council until October 2008. Rodney is a solicitor, a director of Capacitybuilders, a trustee of the Dolphin Square Charitable Foundation, the RNID, the Internet Watch Foundation and the Tavistock Institute. He has been Chief Executive of West Yorkshire County and Westminster City Councils and the Association of Metropolitan Authorities and Chair of the Bradford Health Authority.

Della Cannings

Della M Cannings QPM FRSA BSc MIoD, was born in Exeter, Devon and is a graduate in Mathematical Studies from the University of Bath. Ms Cannings was Chief Constable of North Yorkshire Police 2002 - 2007. She currently undertakes consultancy work and is a trained assessor, and is also a keen gardener, traveller and photographer.

Wayne Cleghorn

Wayne Cleghorn, L.LM., is a Solicitor and the Data Protection Officer for South Gloucestershire Council. He specialises in data protection, privacy, information law, information technology law and aspects of intellectual property law. He also has a professional interest in corporate governance, public law and human rights. His experience includes public and private sector legal services.

Ian Hayes

Ian Hayes is 50 years old and lives in rural Somerset. He was born with Haemophilia and was infected with HIV and Hepatitis more than 20 years ago as a result of treatment failure. Ian was a senior NHS finance manager until 1996. He now has a range of interests centering on patient empowerment, self-management and patient safety. He is a trustee of the Terrence Higgins Trust.

Penny Hill

Penny Hill is currently on secondment with the NHS Information Centre for Health and Social Care, supporting the work of the National Strategic Improving Information Programme for Social Care. The work of the Programme includes the development of information standards for social care, the revision of social care record guidance, and the co-ordination of information developments across a range of policy initiatives. Her previous post was that Information Strategy Manager for Social Care, overseeing a range of Information Services supporting work with both adults and children. She has a wealth of experience in information governance and information management for social care, and has a particular interest in information sharing.

Joan Higgins

Professor Dame Joan Higgins was Professor of Social Policy at the University of Southampton and Professor of Health Policy at the University of Manchester, where she is now Professor Emerita. She chaired the national Patient Information Advisory Group since it began and now chairs the NIGB Ethics and Confidentiality Committee. Joan has been a non executive director in the NHS for over 20 years and was Chair of the Christie NHS Trust from 2002 until 2007 and now chairs the NHS Litigation Authority (NHSLA). Joan is also Chair of the Queens Counsel Selection Panel and a member of the House of Lords Appointments Commission.

Nadeem Khan

Dr Nadeem Khan is Divisional Manager/Associate Director (Research and Development) at UCLH Foundation Trust and is a trustee for a learning disabilities charity. He has previously worked in primary care (strategy and service development), as a consultant with the National Screening Committee and in academia. Nadeem has led collaborative projects with neuropathology centres as part of Brain Net Europe and currently lectures in neurosciences at London University with continuing research interests in adult-onset dementias.

Hilary Newiss

Hilary Newiss is qualified as a solicitor and was a Partner in Denton Hall until 1999 specialising in intellectual property, including confidential information and data protection. She is a former member of the Human Genetics Commission, the Royal Society Working Party Report on Intellectual Property ("Open Science"), the Intellectual Property Advisory Committee and the Ethics and Governance Council of Biobank UK. She is currently a Trustee of the Roslin Foundation.

Sylvia Rothschild

Rabbi Sylvia Rothschild took a degree in psychology at Manchester University and worked for a mental health charity in a therapeutic community, and for a London Borough in adult psychiatric care. She was ordained as a Rabbi in 1987 by the Leo Baeck College and has worked as a community Rabbi ever since. Rabbi Rothschild has continued her interest in medical and community ethics, sitting on a Research Ethics Committee and a local standards committee. She was Chair of the Assembly of Rabbis, and has edited and contributed to books and periodicals on subjects ranging from theology to prayer to ethical matters.

Michael Wilks

Dr Michael Wilks is a forensic physician working in London. He worked as a GP in London between 1977 and 1992. He chaired the BMA's Medical Ethics Committee from 1997 to 2006, and its Representative Body from 2004 to 2007. He is currently President of the Standing Committee of European Doctors (CPME). He is Chairman of the Trustees of the Rehabilitation of Addicted Prisoners Trust (RAPt), a leading provider of addiction treatment in UK prisons.

Members representing Organisations

Allied Health Professions Federation - Gareth Beatty

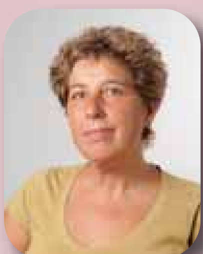
Gareth Beatty qualified as a Podiatrist in 1984 and has worked for the NHS ever since, in a range of posts from domestic porter and nursing auxiliary to his current role as the Clinical Governance facilitator at NHS Richmond. His first professional post was at Guy's Hospital before moving to NHS Richmond. He has been the accredited staff-side representative for The Society of Chiropodists & Podiatrists, and is the Chair for the Partnership Forum for Industrial Relations at NHS Richmond.

The NHS Confederation - Frances Blunden

Frances Blunden is senior policy manager at the NHS Confederation working on informatics, regulation, quality, safety, and patient and public engagement. Frances has extensive experience of research, policy and campaigning on key consumer and health issues across a range of Government and the voluntary sector organisations as well as a lay member of the Council for Professions Supplementary to Medicine. Prior to this she was principal policy adviser at Which? and was also the first Chief Executive of POPAN (now called Witness against abuse by health and care workers).

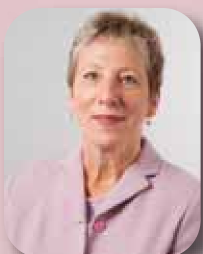
The British Medical Association - Tony Calland

Dr Tony Calland is a general practitioner working on the Welsh border for the past 34 years. He has been a non executive director of Gwent Health Authority and also Chairman of three major BMA committees including currently the Medical Ethics Committee. He was part of the BMA GP team which negotiated the new GP contract in 2003. He has an interest in information governance and is involved in these matters in England and in Wales.



The Academy of Medical Sciences - Carol Dezateux

Professor Carol Dezateux is a paediatrician and currently clinical professor of paediatric epidemiology and Director of the Medical Research Council (MRC) Centre of Epidemiology for Child Health at the UCL Institute of Child Health, London. She is an honorary consultant at Great Ormond Street Hospital for Sick Children NHS Trust and co-director of the UK Newborn Screening Programme Centre. In 2006 she was elected Fellow of the Academy of Medical Sciences.



The Royal College of Nursing - Liz Fradd

Dame Elizabeth Fradd is an independent health service adviser. Until April 2004 she was the Nurse Director and Lead Director for the Review and Inspection programme in the Commission for Health Improvement (CHI). Prior to this appointment she was Assistant Chief Nurse in the Department of Health. Her current portfolio of work includes commissioned independent reviews, the delivery of innovative development programmes and the mentoring of senior personnel. She is currently a Commissioner on the Prime Minister's Commission for Nursing and Midwifery.

The UK Council of Caldicott Guardians - Stephen Hinde

Stephen Hinde is the Head of Information Governance & the Group Caldicott Guardian for the BUPA Group and is a member of the Board Information Governance Executive Committee. Stephen is the past Chairman of the UK Council of Caldicott Guardians, Chairman of the Data Protection Panel of the Association of British Insurers, Chairman of the Confidentiality Working Group of the Independent Healthcare Advisory Services, and Chairman of the Private Medical Insurance Companies Confidentiality Forum. Stephen also represents the Independent Sector on the NHS Scotland Information Governance Network.

The Association of Directors of Adult Social Services - David Johnstone

David Johnstone is Executive Director of Adult & Community Services in Devon and is a member of the Executive Council of the Association of Directors of Adult Social Services. He is extensively involved in the development of electronic care records in health and social care, as a board member of the National Programme for IT and co-chairperson of the Electronic Social Care Record Implementation Board. He has been recently appointed to the NHS Clinical Advisory Team.

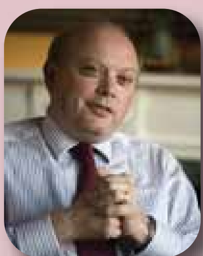
The Local Government Association - Anne McDonald

Anne McDonald is the Programme Director for Community Wellbeing at the Local Government Association (LGA). The Community Wellbeing programme covers local authority activity to improve the wellbeing of adults, not only health and social care, but the wider determinants of health and wellbeing. Facilitation of local partnerships between councils and the NHS is an important strand of the programme. Anne joined the LGA in 2007 from the Department of Health where she was Programme Head in the Social Care Directorate.

The Local Government Association representative member since September 2009 is Andrew Cozens.

The Independent Healthcare Advisory Services - Sally Taber

Sally Taber has worked in the independent sector for 20 years. She has been the Director of Nursing at the Independent London Bridge Hospital, and an advisor to the Royal College of Nursing. She originally qualified as a Registered General Nurse in London and is also a qualified midwife. After a period working abroad, she specialised in renal nursing and pioneered the role of transplant co-ordinator in the renal field. She became the Secretary of the European Dialysis and Transplant Nurses Association and is currently the Director of Independent Healthcare Advisory Services Ltd (IHAS).



The Academy of Medical Royal Colleges - Steve Field

Professor Steve Field has led the Royal College of General Practitioners through Lord Darzi's Review of the NHS, successfully promoting the RCGP "federated" model of patient care. As Chair of the RCGP Education Network, he led the College's radical review of GP training which led to the introduction of the first ever training curriculum for GPs in August 2007. A practicing GP at the Bellevue Medical Centre in inner-city Birmingham, Professor Field is Honorary Professor of Medical Education, University of Warwick, and Honorary Professor in the School of Medicine, University of Birmingham.

Corresponding Advisors

The Royal College of Midwives - Jeanne Tarrant

Jeanne Tarrant qualified as a nurse in 1990 and as a midwife in 1993. Jeanne worked at University College London Hospitals where she was talent spotted by the Royal College of Midwives. She was seconded to the RCM in 2001 as a part time trade union officer/professional advisor while still working at UCLH. In early 2008, Jeanne joined the RCM full time as a team manager for the North of England.

The General Medical Council - Jane O'Brien

Jane O'Brien joined the GMC in 1990, becoming Head of the Standards & Ethics Team in 1995, and Assistant Director in the Standards & Fitness to Practise Directorate in 2006. Jane is responsible for the development of GMC policy and guidance on standards of professional conduct and medical ethics and she has worked on a number of publications for the GMC. Other key areas of focus include professional standards on consent, confidentiality and withholding and withdrawing life-prolonging treatment.

Ministry of Defence - Lionel Jarvis

Surgeon Rear Admiral Lionel Jarvis is Assistant Chief of the Defence Staff (Health). He qualified in Medicine in 1977, thereafter joining the Royal Navy. He trained as a Radiologist, was accredited Consultant in 1990, appointed to RNH Haslar and promoted to Surgeon Commander. He was appointed Defence Consultant Adviser in Radiology 1995-2002 and was promoted to Surgeon Captain in 1999. He also served as an Executive Director of Portsmouth Hospitals NHS Trust. He was promoted to Surgeon Commodore in 2005, and was Director of Medical Policy in the Defence Medical Service Department in MOD. He was appointed Honorary Surgeon to Her Majesty the Queen in 2006.

Strategic Health Authority Chief Information Officers' Council - Graham Folmer

Graham Folmer started his career in information management and technology at the Queen's Medical Centre in Nottingham working for Trent Regional Health Authority. He has a degree in Computer Studies and an MBA from Warwick University. He worked in the private sector for eight years before returning to the NHS. He was Director of Information and Performance Management at Addenbrookes Hospital, then Director of Programme and Service Delivery at the NHS Information Authority. Graham is now Chief Information Officer at East of England Strategic Health Authority previously having this role for Norfolk, Suffolk and Cambridgeshire SHA.

The Medical Protection Society - Nick Clements

Dr Nick Clements has worked in the NHS for 10 years, first as a GP and then as a full time medical adviser to the Benefits Agency. Nick joined the Medical Protection Society (MPS) as a Medicolegal Adviser in 1996, providing medicolegal advice and representation to the doctors from the Leeds office of MPS. He completed an LLB in 1998 and was granted Fellowship of the Faculty of Forensic and Legal Medicine of the Royal College of Physicians in 2008. Nick currently works as the Head of Medical Services (Leeds).

Members of the Ethics and Confidentiality Committee

Professor Dame Joan Higgins, ECC Chair, ***Dr Tony Calland*** and ***Professor Carol Dezateux*** are members of both the NIGB and the ECC and their biographies can be found in the previous section. The other members of the ECC are:

Pauline Brown

Pauline Brown is a senior member of Liverpool PCT's Information Governance Team, where she has worked since joining the Trust from the private sector in 2003. She is an advocate for the rights of individuals particularly to ensure the fair and lawful use of information. She has a longstanding interest in information law and human rights and is an active member of a number of local Information Governance and Freedom of Information Networks.

Michael Catchpole

Professor Michael Catchpole is a Consultant in Public Health Medicine and Deputy Director of the Centre for Infections of the Health Protection Agency. He is a member of the Advisory Forum of the European Centre for Disease Prevention and Control and chairs the Faculty of Public Health's Information and Intelligence Committee. He has an extensive record of managing national surveillance systems for infectious disease and of research in the areas of sexually transmitted infections, HIV and emerging response.

Patrick Coyle

Dr Patrick Coyle is a member of the Clinical Governance Support and Development Unit of the Welsh Assembly Government and was formerly Medical Director of the Glan-y-Mor NHS Trust and Bro Morgannwg NHS Trust and Consultant Surgeon at Neath General Hospital. Patrick was chair of the Security and Confidentiality Advisory Group before it became the DMsG in April 08.

Tricia Cresswell

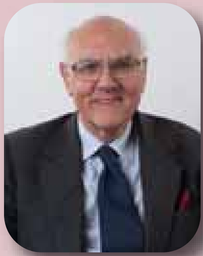
Dr Tricia Cresswell is currently Deputy Medical Director at the North East Strategic Health Authority and a Consultant in Health Protection at the Health Protection Agency North East. Previously she was Executive Director of Public Health for County Durham PCT and Darlington PCT. Prior to that, she held various Director of Public Health posts and was a General Practioner in North Tyneside. She has experience of tackling inequalities in health at policy, strategic and operational level. She has a longstanding interest in the health and wellbeing of children and young people and has published on child health, health services for children and NHS professional practice in child protection.

Fiona Douglas

Dr Fiona Douglas is a Consultant in Clinical Genetics at the Institute of Human Genetics in Newcastle. She is co-author of the guidance document for the Joint Committee on Genetics about consent and confidentiality in clinical genetics. She is the Vice Chair of the Northern and Yorkshire Research Ethics Committee.

Stephanie Ellis

Stephanie Ellis is currently Chair of Camden and Islington Community NHS Local Research Ethics Committee and a Special Adviser to Patient Concern (network of health campaigners) working in areas of patient representation, ethics of consent and information provision.



Denis Pereira Gray

Professor Sir Denis Pereira Gray worked for 38 years in NHS general practice. He was Director of the Postgraduate Medical School of the University of Exeter for 10 years and is a former Chairman of the Academy of Medical Royal Colleges. He was also Chair of the Nuffield Trust.

Michael Hake

Michael Hake is Director of Counterpoint Consulting Ltd. Until March 2005 he was a Director of Social Services: a role held for 14 years. He also had the corporate lead on information governance within his Council. He is also a lay member of the Information Tribunal. He has been a Healthcare Commissioner since 2003 and served on the National Care Standards Commission between 2001 and 2004. His local government service spanned 41 years, mostly within social services and included extensive partnership working with health.

Ros Levenson

Ros Levenson is an independent researcher in health and social care and has published widely on a range of health-related topics. She was formerly director of the Greater London Association of Community Health Councils and has many years experience of working for the involvement of users and carers in the health service. From 1997-2007 she was a non-executive director of a NHS Trust and from 2004-2006 she was a member of the Health Professions Council. She currently serves as a member of the General Medical Council and is also a lay member of the National Commissioning Group.

Roy McClelland

Professor Roy McClelland is Emeritus Professor of Mental Health, Queen's University and a Consultant Psychiatrist at Belfast City Hospital. He is Chairman of the Privacy Advisory Committee for Northern Ireland and former chairman of the Royal College of Psychiatrist's Confidentiality Committee.

Susan Parroy

Susan Parroy is a state registered physiotherapist and has worked as an Independent Project Manager and researcher for 20 years. Sue has recently been working on self referral for patients and she was part of the team behind the Department of Health self referral pilots of physiotherapy. Sue has been a local governor of a NHS Trust, a member of a Medical Research Ethics Committee and is currently working on projects in the south west and Scotland.

Mark Taylor

Dr Mark Taylor is a lecturer in the School of Law and Assistant Director of Learning and Teaching for the Faculty of Social Sciences, at the University of Sheffield. He gained his PhD in 2004 for research into the legal and ethical issues raised by the acquisition and use of genetic information within the contractual context. A Fellow of the Salzburg Seminar (session 392) on 'Biotechnology: Ethical, Legal and Social Issues' he is joint Principal Investigator on an EU FP6 funded project considering privacy and research using genetic data.

Terence Wiseman

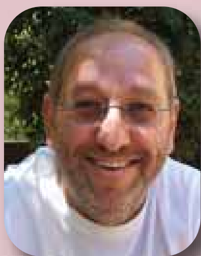
Terence Wiseman is a retired accountant and company director. He is currently a member of Trent NHS Research Ethics Committee and sits on a number of local committees for NHS Lincolnshire and United Lincolnshire Hospitals Trust as a patient representative or lay member. He has been Chairman of Lincolnshire Research Ethics Committee, Vice-Chairman of Lincolnshire Community Health Council and a member of a number of national, regional and local committees.

Members of the Database Monitoring Subgroup (DMsG)

Dr Patrick Coyle, DMsG Chair, ***Terence Wiseman*** and ***Ros Levenson*** are members of both the ECC and the DMsG and their biographies can be found in the section above. The other members of the DMsG are:

Manny Devaux

Dr Manny Devaux was formerly an Assistant Director of Social Services, a London Magistrate and member of South London Health Authority. In 1996 he was appointed by the Privy Council as a member of the General Medical Council and in 2002 became an Associate of the Council and has since chaired Fitness to Practice Panels. He has also served as an Adjudicator for the Criminal Injuries Compensation Appeals Panel. He is also a Hospital Manager for Cygnet Health Care Ltd and in the past has served as a trustee in three separate voluntary organisations in London and in Kent.



Ian Goodman

Dr Ian Goodman qualified from Cambridge University 1982 and is senior partner in the Mountwood Surgery Practice, Northwood, Middlesex. He is Caldicott Guardian for Hillingdon PCT, GP IT advisor to Hillingdon PCT and has been involved with NHS IT projects since mid 1990s including for example, GP member of the RFA 99 project and GP representative on NHS Clearnet initiation project.

Annexe 1: *Principles of the National Information Governance Board for Health and Social Care in decision making and the preparation of advice and guidance*

1. Principles

1.1 The purpose of this document is to record the principles that the National Information Governance Board will use to promote a consistent approach to decision making and the provision of advice and guidance. The following principles provide a framework:

a. People have personal interests and responsibilities as patients, users of services, service providers and also as citizens.

b. Within health and social care services:

- The interests of patients and service users come first;
- Informed consent and personal autonomy should underpin the provision of health and social care; and
- The right information should be available to the right people at the right time to provide individual care whilst preserving confidentiality.

c. It is in people's interests to have:

- Appropriate and accessible care, which promotes health, social welfare and public safety;
- A sound research base on which to build and improve effective services; and
- Well managed and cost effective services.

d. Professionals work within a legal framework and professional guidance.

1.2 These principles will sometimes be in tension with each other. In seeking to resolve those tensions it should be noted that:

a. Allowing service users appropriate control over and access to their own information, and its use, is central to the role of the NIGB;

b. Trust and public confidence in health and social care services should be earned and not assumed;

c. Patients and service users have a right to confidentiality;

d. People's information should be stored and shared in a secure manner;

e. Those providing care must comply with legislation and their professional guidelines;

f. An appropriate balance between individual and public interests must be maintained. In accordance with the Human Rights Act 1998, public interests should only prevail over individual interests when it is necessary that they should do so in order to achieve a legitimate aim in a proportionate manner; and

g. Where decisions are made concerning the balance of individual and professional or public interests, those making those decisions should be accountable and, except where personal details are involved, the basis for such judgements should be made public.

Annexe 1 *continued...*

2. Compliance

2.1 Information Governance in the NHS and social care must ensure compliance with legal requirements and NHS standards as provided within the NHS Confidentiality Code of Practice. This encompasses, in particular:

a. The Data Protection Act 1998, including the requirements for personal data to be accurate and up to date, 'kept secure, adequate, relevant and not excessive' and only used for the purpose for which it is collected in accordance with the fair processing code;

b. The Human Rights Act 1998, especially Article 8 of the European Convention on Human Rights (respect for private and family life);

c. The Common Law in relation to confidentiality;

d. The NHS Care Record Guarantee for England; and

e. The Caldicott Principles (justify the purpose, use on a need-to-know basis, use minimum necessary patient identifiable information).

3. Objectives

3.1 The promotion of health and well-being, and the prevention of harm, are essential components of effective health and social care services.

3.1 In accordance with these principles, the National Information Governance Board should have the following objectives for the decisions it takes and the advice and guidance that it provides. That they:

a. Are practicable and clearly expressed;

b. Benefit everyone fairly;

c. Promote trust and public confidence;

d. Increase transparency about how people's information is recorded, held and used;

e. Support choice and control for patients and service users;

f. Improve people's knowledge and understanding of the way in which their information is used within health and social care; and

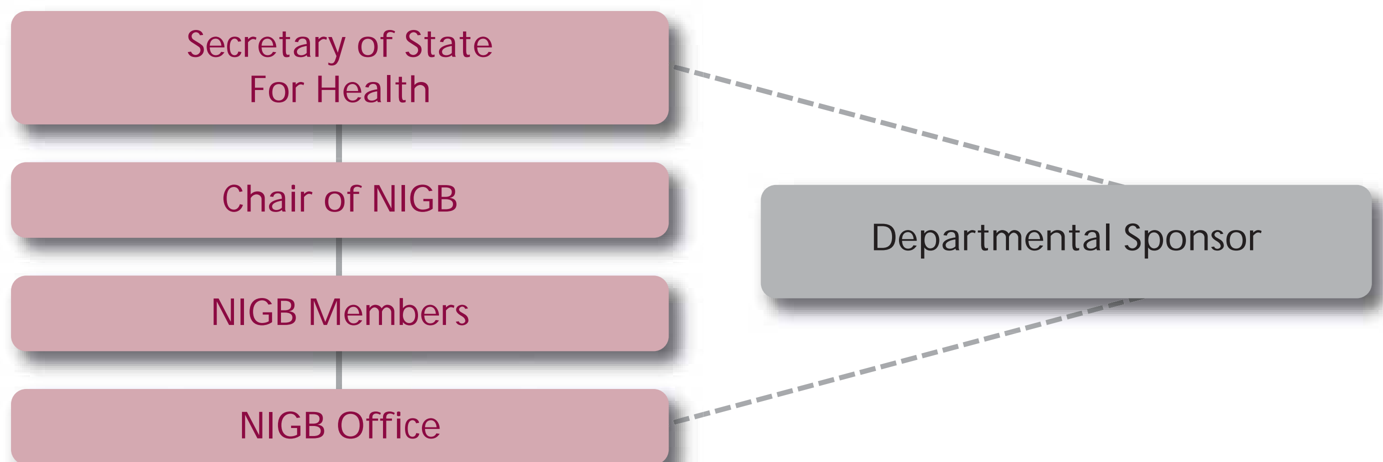
g. Not only support the care provided to people but also the efficient delivery of health and social care services, including governance, public health, health promotion, epidemiology, education and research.

Version 1
February 2008

"Thanks for all your help with our application, the process has been much smoother (and quicker) than I anticipated so it is much appreciated."

Section 251 applicant

Annexe 2: *How the NIGB is governed*



The NIGB is an advisory body (specifically an Advisory Non Departmental Public Body) and reports to the Secretary of State for Health.

Both the Chair and the public members are appointed by the Appointments Commission on behalf of the Secretary of State for Health following a public recruitment campaign. The representative members are from health and social care organisations which are invited by the Secretary of State for Health to be represented on the Board.

The Chair is responsible for ensuring that the Board operates in line with its terms of reference and for the advice that the Board gives. The Chair is appointed for a period of four years and public members are appointed for varying periods between two and four years.

Members of the Ethics and Confidentiality Committee are appointed by the NIGB following a public recruitment campaign and an interview which includes an external assessor.

Whilst the public are not admitted to NIGB meetings the Board operates in a very open way. Within five working days of a board meeting a brief summary of the meeting is put onto the web site and when the minutes have been approved, normally at the next meeting, the minutes and the papers are put onto the website. Shortly we will be publishing members' attendance at meetings and the fees they claim on our website.

The Board also holds an annual public meeting. The day to day business of the NIGB is carried out by the NIGB Office which is also responsible for links between the NIGB and its Departmental Sponsor at the Department of Health. All Arms Length Bodies (ALBs) of the DH have a Departmental Sponsor, whose role it is to help maintain a good working relationship with the Department, ensuring the Board is aware of the departmental objectives and priorities. The Departmental Sponsor of the NIGB is Christine Connelly, Director General of Informatics and Chief Information Officer for the NHS.

Annexe 3: Summary of Applications considered by Ethics and Confidentiality Committee January - September 2009

Reference	Title	Applicant	Outcome	Comments
[PIAG 4-05(g)/2008]	NCASP Pulmonary Hypertension	NHS Information Centre (NHS IC)	Approved after resubmission	
ECC 1-06(b)/2009	Record linkage of GPRD data with cancer data, hospital prescribing data, orthopaedic implants	The Medicines and Healthcare products Regulatory Agency, GPRD Group	Approved with conditions	An application to extend the linkages already approved by PIAG (PIAG 3-04(i)/2006)
ECC 1-06(c)/2009	National Clinical Audit Support Programme (NCASP)	NHS Information Centre (NHS IC) on behalf of the Healthcare Quality Improvement Partnership (HQIP).	Approved after resubmission	Temporarily approved with conditions in March for initial 4-month period, with subsequent approval given in July for a further 8 months.
ECC 1-06(d)/2009	A parental report assessment for cognitive delay in at-risk infants	University of Reading	Declined	
ECC 1-06(e)/2009	Molecular characteristics of paediatric myeloidysplastic syndrome	Great Ormond Street Hospital	S251 not required	
ECC 1-06(f)/2009	A retrospective evaluation of a group intervention of fire setting	West London Mental Health Trust	Declined	
ECC 1-06(g)/2009	Trial of a new PCR system for detection of bacteraemia	Guy's and St Thomas' NHS Foundation Trust	S251 not required	
ECC 1-06(h)/2009	Investigating cancer in the North of England and defining survivorship	University of Leeds	Approved with conditions	
ECC 1-06(i)/2009	Experiences of survivors of Stevens-Johnson/TEN syndrome	University of Birmingham	Declined	
ECC 2-06(a)/2009	Small Area Health Statistics Unit (SAHSU) Health Database	Imperial College School of Medicine and St Mary's	Approved with conditions	
ECC 2-06(b)/2009	CALIBER dataset (Cardiovascular disease research using Linked Bespoke studies and Electronic Records (CALIBER)	University College London	S251 not required	
ECC 2-06(c)/2009	Repeated implantation failure and impaired placentiation after IVF	Central Manchester and Manchester Children's Hospital NHS Trust	Declined	Requesting HFEA data – outside of S251 remit
ECC 2-06(d)/2009	Risk adjustment in Neurocritical Care (RAIN)	The Intensive Care National Audit & Research Centre (ICNARC)	Approved with conditions	
ECC 2-06(e)/2009	Prospective analysis of bruising in children	Cardiff and Vale NHS Trust	Declined	
ECC 2-06(f)/2009	Paediatric Palliative Care in Yorkshire	University of Leeds	Declined after resubmission	

Reference	Title	Applicant	Outcome	Comments
ECC 2-06(g)/2009	Surveillance of Paediatric Bipolar / Disorder in the United Kingdom (UK) and Republic of Ireland (ROI)	Newcastle University	Approved after resubmission	
ECC 2-06(h)/2009	Attribution Data Set	Department of Health	Approved	
ECC 2-06(i)/2009	GP Market Share Analysis	Department of Health	Approved	
ECC 2-06(j)/2009	Investigation into the relationship between OASys and PCL-R scores	HM Prison Service	Declined	Outside of S251 remit – prison database
ECC 2-06(k)/2009	Factors associated with length of stay in a medium secure unit.	East London NHS Foundation Trust	Approved with conditions	
ECC 2-06(l)/2009	Stroke Survivor Needs Survey	Kings College London	Approved with conditions	
ECC 2-06(m)/2009	Improving Stroke Recognition by Ambulance Services (ISRAS): Use of the ROSIER Assessment Tool	London Ambulance Service NHS Trust	Approved with conditions	
ECC 2-06(n)/2009	National Cardiac Arrest Audit	The Intensive Care National Audit & Research Centre (ICNARC)	Approved with conditions	
ECC 2-06(o)/2009	The Study of Suicide in the Criminal Justice System	University of Manchester	Approved	
ECC 2-06(p)/2009	Emergency Stroke Calls: Obtaining Rapid Telephone Triage – Phase 8	University of Central Lancashire	S251 not required	
ECC 3-06(a)/2009	Traumatic Coagulopathy and Massive Transfusion: Improving Outcomes and saving blood	NHS Blood and Transplant	Approved	
ECC 3-06(b)/2009	Monitoring hospital attendance due to self-harm	University of Bristol	S251 not required	
ECC 3-06(c)/2009	Preventable Incidents, Survival and Mortality Study (PRISM)	London School of Hygiene and Tropical Medicine	Approved	
ECC 3-06(d)/2009	Persistent scar problems following caesarean section	Southend University Hospital NHS Trust	Declined	
ECC 3-06(e)2009	West Yorkshire Cardiac Magnetic Resonance Outcome Study	Leeds Teaching Hospital NHS Trust	Approved with conditions	
ECC 3-06(f)/2009	West Yorkshire Primary Percutaneous Coronary Intervention (WY-PPCI) Outcome Study	Leeds Teaching Hospital NHS Trust	Approved after resubmission	

Annexe 3 continued...

Reference	Title	Applicant	Outcome	Comments
ECC 3-06(g)/2009	Pilot study to determine the validity of Hospital Episode Statistics data on the prevalence of paediatric respiratory papillomatosis in England	North Bristol NHS Trust	Partially approved	Access to identifiable HES data approved
ECC 3-06(h)/2009	Wellbeing in the Family: The Impact of Physical Appearance and Health	University of the West of England	Declined	
ECC 3-06(i)/2009	Trends in the incidence and associated factors for childhood intussusception	UCL Institute of Child Health	Approved with conditions	
ECC 3-06(j)/2009	Studies in the molecular pathogenesis of soft tissue sarcomas.	University of Sheffield	Approved with conditions	
ECC 3-06(k)/2009	BRAIN UK (Existing Holdings)	University of Southampton	S251 not required	
ECC 3-06(l)/2009	Sensitivity of Quantiferon in active TB	Central Manchester and Manchester Children's University Hospitals NHS Trust	Declined after resubmission	
ECC 3-06(m)/2009	Prognostic factors in Prostate Cancer	Cancer Research UK	Approved with conditions	
PIAG 1-05(g)/2007	HES and STATS19 one to one matching project	Department for Transport	Approved with conditions	An extension of the previous approval in order to update the data.
ECC 4-15(a)/2009	Risk-adjusted evaluation using existing data	Nuffield Trust	S251 not required	
ECC 4-15(b)/2009	Long-term follow up of a regional secure unit admission cohort 1983 - 2011	Nottinghamshire Healthcare NHS Trust	Approved with conditions	
ECC 4-15(c)/2009	Routine Assessment of symptoms and functioning in Cancer patients	Leeds Teaching Hospital	Approved with conditions	
ECC 4-15 (d)/2009	SAFER 2 - Support and Assessment for Fall Emergency Referrals 2	Swansea University	Declined	
ECC 4-15 (e)/2009	Evaluating stereotactic radiosurgery in brain metastases	UCL Hospitals Foundation Trust	Resubmission pending	
ECC 4-15 (f)/2009	Preventing depression relapse with Mindfulness-based Cognitive Therapy (a psychosocial group-based relapse prevention programme)	University of Exeter	Declined after resubmission	
ECC 4-15 (g)/2009	Pan-Thames Paediatric Intensive Care (PIC) Service Development Audit	City University, Centre for health Informatics	Approved with conditions	

Reference	Title	Applicant	Outcome	Comments
ECC 4-15 (h)/2009	All Wales Perinatal Survey	Cardiff University	Approved with conditions	
ECC 4-15 (i)/2009	Dating fractures in Children under 3 years old	Southampton University Hospitals NHS trust	Declined	
ECC 4-15 (j)/2009	The Molecular Genetics of Dupuytren's Disease (disorder of the hands leading to thickening and contraction of the fascia)	University of Oxford	Appeal pending	
ECC 4-15 (k)/2009	Human Injury Prediction in Blast Trauma	Royal London Hospital	Approved with conditions	
ECC/BPSU 1-06(FT1)/2009	Extreme Hypernatraemia in newborn infants	Bradford Teaching Hospitals	Approved by fast track process	
ECC 1-06(FT2)/2009	Count Me In 2009	Mental Health Act Commission Application	Approved by fast track process	
ECC 2-06(FT1)/2009	Audit and evaluation of the impact of the introduction of the NICE guideline 50 for acutely ill patients	North Tees and Hartlepool NHS Trust	Approved by fast track process	
ECC/BPSU 4-03 (FT1) /2009	Inflammatory Demyelinating Disease Surveillance Study	Institute of Child Health, University of Birmingham	Approved by fast track process with conditions	
MR1165	Enhanced surveillance of individuals identified as at increased risk of v CJD/CJD in the UK due to iatrogenic exposures or other indicators of increased risk	Health Protection Agency	Approved	
ECC 5-07(a)/2009	Infections in Oxfordshire: a Research Database (IORD)	Oxford Radcliffe Hospitals NHS Trust	Approved with conditions	
ECC 5-07(b)/2009	Prescription Event Monitoring	Drug Safety Research Unit	Approved	
ECC 5-07(c)/2009	Record linkage of GPRD data with 1.ALSPAC birth cohort 2. Air pollution data	Medicines Healthcare products Regulatory Agency (MHRA) and the General Practice Research Database (GPRD) Group	Approved with conditions	
ECC 5-07(d)/2009	Referral of Possible Donors to Donor Transplant Co-ordinators Database	NHS Blood & Safety	Declined	
ECC 5-07(e)/2009	A case control study to explore the distribution of lower urinary tract symptoms (LUTS) in older people having fallen	University College Hospitals	Approved with conditions	

Annexe 3 *continued...*

Reference	Title	Applicant	Outcome	Comments
ECC 5-07(f)/2009	Clinical scoring system and or decision rule to identify high-acuity patients from information available prehospital and in the Emergency Department	University of Sheffield	Approved with conditions	
ECC 5-07(g)/2009	Attribution Data Set Data Requirements from the Personal Demographics Service (2009)	Department of Health	Approved with conditions	
ECC 5-07(h)/2009	Descriptive evaluation of the high security dangerous and severe personality disorder (DSPD) pilot services	Imperial College	Approved with conditions	
ECC 5-07(i)/2009	Testing of review criteria to selected NICE guidelines	Newcastle University – Institute of Health and science	Declined	
ECC 5-07(j)/2009	Transitions to Palliative Care for Older People in Acute Hospitals (Census of Care)	University of Sheffield	Declined	
ECC 5-07(k)/2009	Factors associated with Community Treatment Order use	University of Leeds	Declined	
ECC 5-07(l)/2009	Enhanced Recovery Programme	Department of Health	Declined	
ECC 5-07(m)/2009	United Kingdom Gynaecological Oncology Surgical Outcomes and Complications	University College London Hospitals	Declined	
ECC 5-07(n)/2009	Ethnicity in BLPT Service Users	Cambridgeshire and Peterborough NHS Foundation Trust	S251 not required	
ECC/BPSU 5-02 (FT1)	Active Prospective Surveillance for Guillian-Barre Syndrome (GBS) and Fisher Syndrome (FS) in Children	Addenbrooke's Hospital	Approved by fast track process	
ECC 5-02 (FT2)	Palliative Care in Children and Teenagers with Cancer	University of Leeds	Declined	Submitted to full Committee at request of Members
ECC 5-02 (FT3)	Emergency department triage methods for suspected pandemic influenza (The PAINTED Study)	University of Sheffield	Approved by fast track process	

Annexe 4: *Summary of Applications considered by DMsG January - September 2009*

HES Applications

Reference	Title	Applicant	Outcome	Comments
060209-07-b	Consultant Team Summary Report Project (CTSR) Application to expand the scope of the Consultant Activity Log Project approved in September 2008 (AG/72/4/d)	NHS Information Centre (NHS IC)	Approved with recommendations	
060209-07-b	Impact of the Quality Outcomes Framework (QOF) on GP practice	Kings Fund for London	Approved	
060209-07-d	Re-submission of application to November meeting (AG/74/4/a)	York University	Approved with recommendations	
060209-07-e	PROLONG Study	Aberdeen University	Approved	
060209-08-AOB	Request for Legal group of patient and Legal status classification	Dr Foster Unit at Imperial College	Approved	
240409-07-b	Mental Health Minimum Dataset	Dr Foster Intelligence Ltd	Approved	Referred to ECC due to small numbers in extract.
240409-07-c	Studies into the effects of patient choice at the point of referral on competition and hospital outcomes	Centre for Market & Public Organisations Bristol University	Approved	Referred to ECC due to small numbers in extract.
240409-07-d	National Clinical Audit Support Programme (NCASP) Central Cardiac Audit Database (CCAD)	NHS Information Centre (NHS IC) on behalf of the Healthcare Quality Improvement Partnership (HQIP).	Approved	Subject to the ongoing 4 monthly review of the HQIP approval.
170609-6-a	Online access to consultant code	Audit Commission	Withdrawn	
170609-6-b	Online access to legal information	Audit Commission	Pending	
170609-6-e	United Kingdom Collaborative Trial of Ovarian Cancer Screening (UKCTOCS) programme	University College London	Approved	
170609-6-f	Oxford Vascular Study	Oxford University	Approved	
170609-6-g	Whitehall II	University College London	Approved	Extension of existing DMsG approval.
170609-6-AOB	Request for linked mortality data.	University of Liverpool	Approved	Extension of existing DMsG approval.
020909-6-a	Access to HES for the support of CQC functions	Care Quality Commission (CQC)	Approved	CQC have own statutory powers to receive information
020909-6-b	Update of extract years	English Cancer Registries	Approved	English Cancer Registries have S251 to receive identifiable data
020909-6-c	Demand for healthcare services	London School of Economics	Approved	

Central Register Applications

Reference	Title	Applicant	Outcome	Comments
MR1136	A research monitoring system of hospital attendances due to self harm: Mortality following self-harm.	University of Leeds, Institute of Health Sciences	Approved	
MR1142	Derbyshire Mental Health Trust – Self-harm monitoring project – Mortality following Deliberate Self-harm	Derbyshire Mental Health Trust	Approved	
MR1147	E-ECHOES: Ethnic - Echocardiographic Heart of England Screening Study	University of Birmingham, Department of Primary Care Clinical Sciences	Approved	
MR1151	PREPARED-UK: Prospective Registry and Evaluation of Peripheral Arterial Risks, Events and Distribution in the UK	Royal Brompton Hospital	Approved	
MR1152	Exploring the determinants of outcome following major surgery	University College Hospital NHS Trust	Approved	
MR1153	Pallister-Killian Study	Wessex Clinical Genetics Service	Approved	
MR1157	Knee Pain Progression and Risk Factors	Nottingham City Hospital	Approved	
MR1145	Obtaining standardised follow up and cause of death information for the BRACE memory clinic database	BRACE Centre	Approved	
MR1149	Risk factors for suicide in prisoners: mortality following near-lethal self-harm in custody	University Department of Psychiatry, Warneford Hospital	Approved	
MR1158	Improving the care pathway for heart failure in residential care (HFinCH)	School of Medicine and Health, University of Durham	Approved	
MR1160	Parkinsonism: Incidence and Cognitive Heterogenity in Cambridge. The PICNICS study.	Cambridge Centre for Brain Repair	Approved	
MR1155	Which oxygen saturation level should be used for very premature infants? A randomised control trial (BOOST-II UK)	NPEU, University of Oxford	Approved	
MR1163	Standardisation of Breast Radiotherapy (START) Trials A and B.	The Institute of Cancer Research	Referred to ECC	Consent not fully in place
MR1166	Evaluation of Mammographic Surveillance Services in Women under 50 with a family history if breast cancer.	Breast Test Wales	Approved	

Reference	Title	Applicant	Outcome	Comments
MR1156	European Male Ageing Study	Andrology Research Unite, University of Manchester	Approved	
MR1162	British Breast Cancer Study	London School of Hygiene and Tropical Medicine	Approved	
MR1164	Asymptomatic Carotid Surgery trial	Department of Vascular Sciences, St George's University of London	Approved	
MR1170	COIN Study	Medical Research Council, Clinical Trials Unit	Approved	
MR1172	Clinical Evaluation of Magnetic Resonance imaging in Coronary heart disease (CE-MARC)	Leeds University	Approved	

Notes

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