Consultation on Public, Patients, and other interested parties views on Additional Uses of Patient Data

Purpose

We are gathering people's views to help us make important decisions about the ways we can use information we collect about patients when we give them care. We call this information patient data. Patient data is mainly used to provide care and treatment but can also have **additional uses** such as **research, auditing the quality and safety of care,** management planning etc. This consultation is focusing on additional uses.

Audience

The consultation is seeking the views of the general public, patients, patient groups, NHS staff, the research and ethics community, regulators and professional bodies. In addition, we are contacting a number of groups directly to invite them to respond to this consultation. The full list can be found in a section at the end.

Background

Patients' records have always been used for purposes other than providing care, for example for planning new NHS services and for medical research. Because patient records will increasingly be held on computer rather than paper, it is becoming easier to collect and use patient data for these purposes. Normally data used in these ways does not show the individual patients' details, but sometimes it is not useful unless it identifies individual patients. The following questionnaire seeks your views on when and how the NHS should use patient data for additional uses.

Further information about the background to this consultation can be viewed on the NHS Connecting for Health website.

http://www.connectingforhealth.nhs.uk/susconsultation/systemsandservices/research/consultation/background

Confidentiality of responses to the consultation - Please read this section and respond as appropriate

In this consultation you can respond anonymously, you don't need to give your name. If you are replying on behalf of an organisation, then we need to know the name of the organisation and it would also be helpful to know your name. In our report of this consultation, we will summarise responses and not publish them in any way that will identify individual respondents. However,

sometimes we may be asked to make the responses we receive available to others in full. When that happens, how we respond is governed by various access to information laws - primarily the Data Protection Act 1998 and the Freedom of Information Act 2000 (FOIA). These two laws try to strike the right balance between protecting individual privacy and the public's right to know.

If someone should apply under FOIA for information about individual responses:

- we will not normally disclose the identity of **someone responding as an individual patient or member of the public or as an individual member of NHS staff, including clinicians**.
  - If, however, you fall into any of these categories and are happy for your identity to be disclosed in response to a Freedom of Information Act request, please tick this box. ☐

- we will normally disclose the name of a **person responding on behalf of an organisation** and the name of the organisation.
  - If there are reasons not to identify the person responding, please provide them below and we will consider them when meeting a Freedom of Information Act request. Note that the automatic disclaimer generated by your email system is not adequate.

Please enter your response, if applicable

Completing the survey

The survey contains 23 questions over five sections and it should take you no more than 30 minutes to complete. We are grateful to you for helping us in this important way.

The survey begins by collecting background information about you, without identifying you as an individual. It then sets the scene so that you can give us your opinion on additional uses of patient data other than for care and treatment. It collects your views using four stories about an imaginary patient, Pam Smith, that describe some additional uses of data.

Please complete this questionnaire by 10th December 2008 and return by email to: christina.brand@tribalgroup.co.uk
If you have any questions, please call Chrissy on 07717 881633.

Glossary of terms

A glossary of terms used in the consultation is attached to this questionnaire. Terms in the glossary are underlined throughout the paper and are explained in a section at the end.

What will happen with the consultation findings?

The findings will be written up in a full report. The report will compare the responses of different groups and organisations. Views will be summarised in a way that does not identify individual respondents. . The results will be used to help shape the future development of the NHS Care Records Service. Copies of this document and a shorter summary document will be made available on the NHS Connecting for Health website *(*www.connectingforhealth.nhs.uk/susconsultation in February 2009*).*

About you – to help us compare the views of different types of people, please answer as many of the questions below as you feel comfortable with

1. Please select the option below that best describes you.

Professional body

If other, please state:

2. Please say if these are your own views or if you are representing an organisation or group:

The views of my organisation, please state below

Faculty of Public Health

3. What is your age band?

40-59

4. What is your gender?

Male

5. What is your ethnic origin?

White - British

If other please state below,

Please enter your response, if applicable

6. What is your religion?

Not specified

7. Do you consider yourself to belong to any of the groups below?

Tick all those which apply.

- ☐ Lesbian/gay/transgender groups
- ☐ Migrant worker
- ☐ Permanently sick or disabled
- ☐ Gypsy/Traveller

Controls of additional uses of patient information

There are strict controls on how the NHS uses patient information. All research with patients or their information has to be approved by an NHS Research Ethics Committee before it can start. In addition, the NHS organisations that hold the patients' records have to give permission.

Anyone who needs to use identifiable patient data from the NHS Care Records Service without getting patients' consent has to put their case to an independent body known as the Patient Information Advisory Group (PIAG). The PIAG has powers, set out by Parliament under section 60 of the Health and Social Care Act 2001 to allow the use of patient identifiable information for medical and medical research purposes without individual patient consent. This issue is explained in more detail later in this document.

Patient and Public Scenarios

We want your views on how we use your electronic patient record. The NHS needs to use patient information for important things other than patient care - such as research and planning. This paper will ask you questions, based on the story of Pam Smith, our imaginary patient.

Before you begin, we need to explain a few things about patient information, the ways it can be used, and how we propose to ensure we use it safely.

Meet Pam Smith (our imaginary patient)

Pam Smith is 48 years old and has had diabetes for 10 years. She visits her GP at least three times a year and sometimes has to attend her local hospitals.

Meet the NHS Care Records Service

Pam's GP holds an electronic record of all Pam's visits on the practice computer system. Each of Pam's hospitals also holds a record of all her visits on their own computer systems or on paper records. Information about Pam is normally shared by letter, secure email or secure fax.

Modern computer systems, called the NHS Care Records Service, are being introduced in the NHS over the next few years. The computer systems are designed to hold Pam's information securely and in confidence. They can be used by those treating her wherever she needs care. They can also make it easier to collect information on a group of patients and use it in other ways to improve health and care.

The NHS Care Records Service will use the strongest national and international security measures for handling patient information. Though no paper or computerised record system can ever offer 100% guarantees, there are very strong measures in the new system to help ensure that information is stored safely, stays private and is accessed appropriately. By law, everyone

working for or on behalf of the NHS staff with access to Pam's records must respect her confidentiality and keep all her information secure. All staff in the NHS have a duty of confidentiality and will only be able to access her data if they have been authorised to do so.

We use Pam's information for more than Pam's care

As well as for Pam's care, information held in her records might also be used for other purposes known as **'additional uses'.** Here are two examples:

- the NHS might want to compare the results of surgery for eye problems related to diabetes at different hospitals **(a 'clinical audit')**.
- researchers might be asked to find out what puts people at risk of getting diabetes so that they can develop new treatments or even prevent people getting diabetes in the first place

Some additional uses may directly benefit Pam; some may benefit others in the future, and others may benefit society as a whole. Apart from clinical audits and research, other additional uses might include:

- protecting the health of the public
- planning and organising NHS services
- managing NHS spending
- dealing with complaints about healthcare, and
- teaching healthcare workers.

Pam will be able to hide sensitive information in 'Sealed Envelopes'

There are strict controls in the NHS to ensure that only people treating Pam see her information and only see what their job permits them to. Pam can also ask the team treating her to mark certain information in her records as not to be shared with anyone else, the same as putting it in a **'sealed envelope'**. She will have two choices for sealing. Either way, the team that sealed the information for Pam can always see it.

- **If it is just 'sealed'**: other people are able to see that there is hidden information in the record but not what it is. Pam can give a one off permission for someone to look at it.
- **If it is 'sealed and locked'**: no-one else will know it exists.

A couple of months ago, Pam was treated for depression. She doesn't want anyone but her own GP to know it. So, she has asked her GP to seal all the notes about her depression.

Pam's information can be made available to others in three ways

Information in Pam's records can be made available to others in three different forms:

- **'Patient identifiable' information** – records containing personal details such as Pam's name, address, postcode, and NHS number. Patient identifiable information is mostly used to give Pam care. However sometimes additional uses may need identifiable data, for example, when linking information about Pam held on computer with paper records.
- **'Anonymised' information** - records with no patient identifiers. The additional uses described above mostly use **anonymised** data and do not allow a patient's different records to be linked..
- **'Linked anonymised' information** – Pam's personal details are replaced with a code unique to Pam's records (for example it might be '12AA56JH56N-0111') that allows information from her different records to be linked without knowing who she is. This is also called **'pseudonymised' or 'coded' information.**

If you want to see examples of records please see the end of this paper.

Normally, Pam will be asked for consent if the data is identifiable

Most of the time Pam's data is used for the purpose of providing her with care. Sometimes the NHS may need to use Pam's identifiable data for other additional uses.

Normally the law does not allow Pam's identifiable data to be used without her **consent**. **Consent** means that Pam is asked if she agrees to the use of her information. However there are times when the NHS has a legal duty to pass information on without **consent** such as:

- Births of children
- Reporting of infectious diseases
- Reporting gunshot wounds to the police
- When required by a court order.

The NHS can make Pam's information available for additional uses without her **consent** so long as it is anonymised. Anonymised patient information is already used for both research and audit. The NHS Care Records Service will make it much quicker and easier to anonymise patient information.

Sometimes, with special permission, identifiable information can be used without patient consent for audit and medical research. .

An 'Information Custodian' could oversee the use of Pam's information

It is suggested that in the future, there could be an organisation performing the role of an **'Information Custodian'** to safeguard the use of patient data for additional uses. When someone wants to use Pam's identifiable information for uses other than providing her with care, they will have to apply to an **'Information Custodian'**. The custodian would be a specially chosen body that is able to turn patient identifiable information into 'anonymised' and 'linked anonymised' information and oversee who has access to it. There will be clear, published rules governing how the custodian operates and decides who can and cannot use Pam's information.

There is a small chance of a patient being identified from information that has been anonymised, for example if someone has a very rare condition. The risk may be slightly higher with linked anonymised data. One of the roles of the **'Information Custodian'** is to ensure the risks are as small as possible.

Legislation would need to be passed by Parliament to create this role.

Example 1: Using Pam's Anonymised Data

Pam's information is **'anonymised data'** when all the information that could identify her (e.g. name, address, date of birth and NHS identifier) is removed.

A health planner may wish to know how many people locally have been diagnosed with diabetes. A researcher might be asked to find out how many people with diabetes also have depression, and if so which condition happened first? Pam's episode of depression is in a **'sealed envelope'** in her records so nobody outside of her GP practice will know about it. The researcher would want to be able to count Pam's episode of depression in his research but doesn't need to know who she is. Without Pam's information, the research may be less complete. The plan is that the new electronic system will be able to use information from sealed envelopes in an anonymised form for purposes like research, without having to seek permission. Sealed envelopes will provide patients with a new way to control how information about them is shared. We would like to understand whether you believe that anonymised information that has been sealed should be subject to special restrictions on when it can be used for additional purposes.

8. Should anonymised data in 'sealed envelopes' be used for additional purposes if it is anonymised?

Yes

If yes, but only with the consent of the patient, go to question 9 otherwise go to question 10

9. If people should be asked for their consent to share anonymised data in a 'sealed envelope', when should they be asked?

Please select option

If only in specific circumstances, please explain

10. Do you have any concerns or comments about the use of data held in sealed envelopes for research or other purposes apart from care?

While the question relates specifically to 'sealed envelopes' the response is equally applicable to all patient data, irrespective of whether it is held in a 'sealed envelope' or in the main body of the clinical record.

Patients may be reluctant to disclose certain information if they know that it may be used, even in an anonymised format. Rigorous controls will be required to avoid the risks of "deductive disclosure" of patient identity from use of anonymised data. With any individual level data, even if anonymised there remains a risk, albeit small, that in some cases, the data will remain potentially identifiable. Furthermore uses such as medical research, which involve disclosure outside of the infrastructure of the NHS raise issues in relation to the oversight of anonymised (and linked anonymised) data to ensure it is not combined with other data which would result in some of the data becoming identifiable.

11. Although strictly speaking individuals have no legal right to restrict how information that has been effectively anonymised may be used, it is important that we understand and where possible address people's concerns. Do you have any concerns or comments about the use of anonymised data for research or other additional uses?

See above. The use of anonymised data from sealed envleopes should be subject to approval by the National Information Governance Board or a delegated authority thereof. Furthermore, the use of anonymised (or pseudonymised) data should be subject to the following caveats:

i) That the data is effectively anonymised / linked anonymised, so that it

is not identifiable to the recipient.

ii) That those accessing patient level data undertake only to combine the data with other data where approved to do so and not with the intention of identifying individuals.

iii) That those accessing the data undertake not to disclose patient level data to third parties without approval from the original data controller and other approving bodies.

iv) That patients are provided with clear information about the additional uses of patient information, including where where anonymised / linked anonymised data will suffice and where identifiable data is needed.

Example 2: Using Pam's Linked Anonymised Information

Linked anonymised information replaces Pam's personal details with a code that enables her records to be linked across the NHS or over time without identifying her.

Some research studies need to link Pam's hospital and GP records or follow her progress over time. In the past researchers wanting to link Pam's records in these ways would need her personal details to match them. In the future the new electronic systems will make it possible for the researchers to link Pam's records without seeing her personal identifying information.

Linked anonymised information would be needed to answer questions such as:

> What is the long term survival rate of diabetic patients taking different types of insulin?
>
> How often does screening of diabetic patients need to be carried out to be effective?
>
> How many patients with diabetes have been waiting more than 12 weeks for treatment?

12. Should linked anonymised data in 'sealed envelopes' be used for purposes other than care?

Yes

If yes, but only with the consent of the patient, go to question 13 otherwise go to question 14.

13. If people should be asked for their consent to share linked anonymised data in a 'sealed envelope', when should they be asked?

Please select option

If only in specific circumstances, please explain

14. Although strictly speaking individuals have no legal right to restrict how information that has been effectively anonymised may be used, it is important that we understand and where possible address people's concerns. Do you have any concerns or comments about the use of linked anonymised data for research or other additional uses?

As for the previous questions, this response relates equally to data derived

from any part of the clinical record.

The risks of "deductive disclosure" are greater for longitudinal (linked) data, and therefore controls need to be tighter. Use of linked anonymised information should be regulated, with "use-by-use" approval, by a suitably authorised body.

Anonymisation of regulation processes should be appropriate to the level of geography (eg. Lower Super Output Areas). For longer term trends, when local boundaries change, even if data are never given out for instance below PCT or LA level, LSDA data are still needed to cope with changing boundaries over time.

Example 3: Using Pam's Patient Identifiable Data

Sometimes information that identifies Pam is used for research and audit. This is normally with her consent. Some research questions can only be answered by using identifiable information but for a variety of reasons it might be too difficult for the researchers to get consent from each patient. For example:

- The information is very old
- There are too many patients involved
- Approaching individual patients may cause more distress or harm than not seeking consent - for example, a study needing to use old data about termination of pregnancies could upset the women who have put it behind them or alert others who did not know.
- Seeking consent may result in biased findings if, for example, large numbers can no longer be traced to ask for consent;

All research first has to be approved by an **NHS Research Ethics Committee** and the organisations who hold the records. If patient identifiable data is used, normally researchers will approach each suitable patient and ask for their consent. When consent cannot be sought, an independent body known as the **Patient Information Advisory Group (PIAG)** reviews the research. PIAG have to be convinced that the research is in the interests of patients or the wider public and that seeking consent from each individual would be much too difficult.

An example of research that might use information with patient identifiers without consent is as follows:

A researcher has been asked to find out if babies born with a low birth weight are more likely to develop diabetes later in life. This type of study might help doctors better understand the factors that lead to diabetes and may help prevent it in the future.

The best way to carry out this study would be to match Pam's birth records from the 1960s, which are on paper, with her electronic records today. The researchers would need to identify Pam in order to match her records. They do not need to contact Pam as part of the research. Getting consent from her and every other individual is likely to be much too difficult because of the number of people and the age of the records. Therefore they wish to do it without her consent.

15. Should identifiable data be used for research or other purposes without explicitly asking permission from the patient?

Yes but only if a group like PIAG review it

Note above "Probably but it depends" is that it depends on the type of research or who the researcher is.

If you select this please explain.

In considering whether identifiable data can be used without consent on grounds of the public interest, there is a need to balance the public interest in favour of disclosure with the public interest in maintaining public trust in a confidential service. Factors that need to be considered and weighed in relation to this are: a. The extent of the disclosure i.e. how identifiable the data is and how long it needs to be held in identifiable form. b. The relative sensitivity of the data and the degree of distress that may be caused both by the failure to seek consent and on the other hand by seeking consent. c. The practicality and reasonableness of seeking consent for the disclosure and whether those arguments hold for all of the individuals whose data may be used. d. Whether seeking consent would lead to significant data bias because it is a rare condition and very small numbers of cases are involved. e. Whether there are other feasible ways of achieving the same ends without using identifiable patient information.

If "No, never" go to question 16 otherwise go to question 17

16. If people should be asked for their consent to share identifiable data, when should they be asked?

Please select option

Note above "People should be allowed to specify" is that People should be allowed to specify that it is only used in certain circumstances e.g. for particular kinds of research.

If you select this please explain.

Please enter your response, if applicable

17. Do you have any concerns or comments about the use of patient identifiable data for research or other purposes without your consent?

Use of identifiable data without consent should only be permitted if the principles currently followed by PIAG apply. Indiscriminant use of identifiable patient data without consent is likely to damage doctor/patient relationships, and ultimately would damage research and public health.

This consultation does not differentiate between different types of additional use (e.g. for administration purposes, for audit, research, etc), and it may well be that patients will have different views on the acceptability of these different types of use.

Example 4: Using Patient Identifiable Data for selecting and inviting patients into trials

Researchers have been asked to test a new medicine for diabetes and are looking for suitable patients to join the study. They do not have Pam's consent to look at her records to see if she is suitable and they cannot contact Pam directly. The PIAG established an ethical principle of patients being contacted by their doctor rather than by a researcher. So researchers have to rely on Pam's GP or someone else treating her to identify her for the study and contact her, but this can be very time-consuming. As a result, Pam may not be offered the chance to take part in the study even though she might want to.

Alternatively, the researchers can apply to PIAG for special permission to have the records searched to identify suitable people for their study. The researchers would then be able to see Pam's details, and they can write to her and invite her to join their study.

18. If a study has been approved by an NHS Research Ethics Committee and the NHS organisation holding the patients' health records also agrees, should it be possible for researchers to search patients' records to find suitable people to take part in the study?

Yes, but only with PIAG support

If you have stated it depends please explain below

If you have stated it depends please explain

19. Should it be possible to put flags on records to show whether patients are willing to be contacted directly by researchers?

Yes possible but only for certain types

Note above "Yes possible but only for certain types" is for certain types of research or researchers.

If you have selected this please explain below

The use of flags in this way is a form of consent. It is doubtful that consent to disclosure of details about a disease or condition can be seen as holding in perpetuity, nor that consent could be sufficiently informed to cover all possible circumstances. Short term flagging for a specified range of purposes is probably possible. However, longer term flags for historical exposures, when it is impractical to gain consent now, is probably permissable (eg. radiation

cohorts).
20. Do you have any concerns or comments about the use of patient identifiable data for the purpose of inviting patients to join future studies or the use of flags?
The selection of patients for studies is often on criteria relating to a particular disease or condition. Disclosure that an individual is eligible for a study is therefore, of itself, disclosure of sensitive personal data, and should be regulated in the same way as other uses of sensitive personal data.

Example 5: An Information Custodian looks after additional uses of Pam's information

We introduced the idea of an 'Information Custodian' who might look after patient information and be responsible for making it available for uses other than patient care (such as planning care or research). The Information Custodian would act as a guardian to control data access and act as a safeguard. Legislation would be needed to create this role of Information Custodian.

21. Do you agree that the idea of an 'Information Custodian' is a useful one?

Quite useful

Please explain your answer:

Information custodians could reduce the number of third parties requiring access to identifiable data. However, a mechanism (PIAG approval) or legislation would be required to establish such custodians, and it is unlikely that their existence would prevent the continued need for PIAG approval for uses of data not held by those custodians.

Below are some of the tasks that the 'Information Custodian' might do:

- manage the way patient data is anonymised
- link data from different sources using a code and then remove the identifiers
- perform data quality checks
- receive applications from researchers and others who want to use patient data and decide which ones to allow

22. Are there any other tasks that you would like the Information Custodian to do? Please write in:

Please enter your response

23. Have you any concerns or comments about the use of an 'Information Custodian'?

Information custodians would need to be subject to appropriate legislative support and regualtion. It would be important for any such custodian to have:

a.	Adequately and appropriately defined data processing rights.
b.	A secure legal basis.
c.	Appropriate and independent oversight.

Finally the NHS Care Records Service will develop over time and will continue to need input from the public and others in the future. Would you like to be consulted in the future? If so, please give your contact details below:

Name:	Please enter your details, if applicable
Address:	Please enter your details, if applicable
Email:	Please enter your details, if applicable
Telephone number:	Please enter your details, if applicable

Please note that the personal information that you provide us with here will only be used to contact you for future consultation activity and will not be used for any other purposes. Responses from individuals will not be identified in the consultation report.

Glossary

Additional Uses

These are also sometimes known as 'secondary uses' and include:

- Research
- Clinical audit
- Planning and organising NHS services
- Managing NHS spending
- Dealing with complaints about healthcare
- Teaching healthcare workers

Anonymous

Information which is anonymous or anonymised has had all the personal details removed which identify the individual. For example, anonymised information would not contain the individual's name, address, telephone number, full postcode, or NHS number.

Consent

Patients may be asked if they consent or agree to particular activities such as treatment. They may also be asked to consent to additional uses of their patient information, such as research. Consent to take part in research may take the form of explicit informed consent, usually sought face to face and confirmed in writing. Consent is sometimes implied. Implied consent may be based on posters in waiting rooms or letters inviting patients to opt out if they so wish.

Information Custodian

This role will involve safeguarding patient data for additional uses. Someone wanting to use patient data for other uses, apart from treatment or care of the patient would have to apply to an 'information custodian'.

Linked anonymised

Information which is known as linked anonymised is often known as 'pseudonymised' or 'coded'. Linked anonymised data has had all the main identifiers (personal information such as name, address etc) removed but has been allocated a code number which enables the data controller to link the data back to the individual. This code would be meaningless to anyone else. The code allows the information custodian to link the information to other data sets which means that it is possible to follow the progress of a patient over time.

NHS Research Ethics Committee

This is an independent body which meets on a monthly basis to review research studies within the NHS. Approval from a research ethics committee is essential for any research study in the NHS which involves patients or their data. The committees are made up of one third 'lay' ('lay' member means a member of the public) members and two thirds clinical members. The members consider the ethical issues of each study presented to them.

Patient Identifiable Information

Patient Identifiable information contains personal details such as name and address or NHS number which would allow someone looking at the information to identify the individual. Patient identifiable data is used mostly to deliver care and treatment to patients.

Patient Information Advisory Group (PIAG)

There are some situations where informed consent cannot be obtained. For example, important research projects may involve tens of thousands of patients where contact would be impracticable. The essential nature of some of this research means that the public good outweighs issues of privacy. Some patients are not capable of giving consent, but the health service still needs to know about them and their conditions. Sometimes excluding those who refuse consent might bias data collection to the extent that it loses all value. Section 60 of the Health and Social Care Act 2001 provides a power to the Secretary of State to ensure that patient identifiable information needed to support essential NHS activity can be used without the consent of patients. The power can only be used to support medical purposes that are in the interests of patients or the wider public, where consent is not a practicable alternative and where anonymised information will not be enough.

The Patient Information Advisory Group was set up to provide advice on issues involving the use of patient information, to oversee arrangements created under Section 60 of the Health and Social Care Act 2001 and to advise the Secretary of State. Its membership is drawn from patient groups, healthcare professionals and regulatory bodies and it meets once every three months.

Sealed Envelopes

These can take two forms:

- 'sealed information' – this exists as hidden information which normally only members of a patient's immediate clinical care team can see. Other healthcare workers can see that there is hidden information but cannot see what it is. They can ask for permission from the patient to see the hidden

information but this can be refused. In an emergency, if you are unable to give your permission, other people can open the hidden information but have to justify the decision.

- 'sealed and locked information' – nobody outside of the clinical care team will even know that this hidden information exists. Even in an emergency, sealed and locked information will not be available to other people.

Example of 'Patient identifiable' patient record

GP Summary Patient Record for Pam Smith

Title:	Mrs
First Name (s):	Pamela Anne
Last Name:	Smith
Address1:	52 Paradise Square
Address2:	Suburbia
Town:	Mooretown
County:	Moorshire
Post Code:	MN37 6AJ
Home telephone no:	0932 56478 9838

Further Details:	
Date of Birth:	25.02.1960
Gender	Female
Height:	1.76 m
Weight:	63.5 kg
Smoker:	No

NHS Reference Number: ABCD12345678

Medical History	Start date	Follow-up
Diabetes Type 1	Since 1992	3 monthly checks
Influenza	30 Jan 1997	
Urinary Tract Infection	16 Nov 1999	
Urinary Tract Infection	20 July 2001	
Acute back pain	3 March 2003	
Chest Infection	10 Feb 2004	
Depression	14 Nov 2007	3 monthly checks

Current Prescriptions:
Insulin
Fluoxetine

Allergies:
Ibuprofen
Penicillin

Surgery:	
Tonsillectomy	1968
Wisdom Teeth Extraction	23 March 1974

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Example of 'Anonymised' patient record

GP Summary Patient Record

Title:	
First Name (s):	
Last Name:	
Address1:	
Address2:	
Town:	Mooretown
County:	Moorshire
Post Code:	MN37
Home telephone no:	

Further Details:	
Date of Birth:	1960
Gender	Female
Height:	1.76 m
Weight:	63.5 kg
Smoker:	No

NHS Reference Number:

Medical History	**Start date**	**Follow-up**
Diabetes Type 1	Since 1992	3 monthly checks
Influenza	30 Jan 1997	
Urinary Tract Infection	16 Nov 1999	
Urinary Tract Infection	20 July 2001	
Acute back pain	3 March 2003	
Chest Infection	10 Feb 2004	
Depression	14 Nov 2007	3 monthly checks

Current Prescriptions:
Insulin
Fluoxetine

Allergies:
Ibuprofen
Penicillin

Surgery:	
Tonsillectomy	1968
Wisdom Teeth Extraction	23 March 1974

Supported by the Department of Health

DH Department of Health

Example of 'Linked anonymised' patient record

GP Summary Patient Record
Code: 1433451328

Title:	
First Name (s):	
Last Name:	
Address1:	
Address2:	
Town:	Mooretown
County:	Moorshire
Post Code:	MN37
Home telephone no:	

Further Details:	
Date of Birth:	1960
Gender	Female
Height:	1.76 m
Weight:	63.5 kg
Smoker:	No

NHS Reference Number:

Medical History	Start date	Follow-up
Diabetes Type 1	Since 1992	3 monthly checks
Influenza	30 Jan 1997	
Urinary Tract Infection	16 Nov 1999	
Urinary Tract Infection	20 July 2001	
Acute back pain	3 March 2003	
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Depression	14 Nov 2007	3 monthly checks

Current Prescriptions:
Insulin
Fluoxetine

Allergies:
Ibuprofen
Penicillin

Surgery:	
Tonsillectomy	1968
Wisdom Teeth Extraction	23 March 1974

Supported by the Department of Health

Consultation Criteria

This consultation follows the 'Cabinet Office Code of Practice', in particular we aim to:

- consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy;
- be clear about what our proposals are, who may be affected, what questions we want to ask and the timescale for responses;
- ensure that our consultation is clear, concise and widely accessible;
- ensure that we provide feedback regarding the responses received and how the consultation process influenced the development of the policy;
- monitor our effectiveness at consultation including through the use of a designated consultation co-ordinator; and
- ensure our consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

The full text of the code of practice is on the Cabinet Office website at:

http://bre.berr.gov.uk/regulation/consultation/code/index.asp

Comments on the consultation process itself

Any comments or complaints about this consultation (but not responses to the consultation itself) should be sent to:
Consultations Coordinator
Department of Health
Room 2N16
Quarry House
Quarry Hill
Leeds
LS2 7UE
Email: Mb-dh-consultations-coordinator@dh.gsi.gov.uk

Please do not send your consultation responses to this address.

List of Groups to be consulted

Below is a list of all the groups that we are contacting directly to invite them to submit a response to this consultation. If there are any other groups that you think we should also be consulting please write in the name of the group(s) in the box below.

Please enter group name(s), if applicable

Organisations
Patients and the public
Action Against Medical Accidents
Age Concern
Allergy UK
Alopecia Awareness
Alopecia UK
Alzheimer's Society
Amnesty International UK
Arthritis and Musculoskeletal Alliance
Arthritis Care
Asthma UK
Backcare
Breast Cancer Care
British Association of Skin Camouflage

British Deaf Association
British Ethnic Health Awareness Foundation
British Legion
British Lung Foundation
British Red Cross
Cancer Backup
Cancer Research UK
Carers UK
Changing Faces
Children's Society
Choices for Families of Children with Arthritis
Citizen's Advice Bureau
Cleft Lip & Palate Association
Coalition on Sexual Orientation
Commission for Patient and Public Involvement in Health
Contact a Family
CSIP Experts by Experience
Cystic Fibrosis Trust
DebRA
Depression Alliance
Derbyshire Gypsy Liaison Group
Developing Patient Partnerships (DPP)
Diabetes UK

Disability Living Foundation
Dr Foster
Ectodermal Dysplasia Society
EDS
EURIM The Information Society Alliance
Fibromyalgia Association
Foundation for People with Learning Disabilities
Gender Identity Research and Education Society
Genetics Interest Group
Gypsy Roma Traveller Leeds
Headlines: The Craniofacial Support Group
Help the Aged
Herpes Viruses Association
INVOLVE
Liberty and the Civil Liberties Trust
Local Involvement Networks (LINks)
Long Term Medical Conditions Alliance
LUPUS UK
Lymphoma Association
Marie Curie Cancer Care
Mental Health Foundation
MIND
Multiple Sclerosis Society

Muscular Dystrophy Campaign (MDC)
Myositis Support Group
National Ankylosing Spondylitis Society
National Association for Patient Participation (NAPP)
National Childbirth Trust
National Eczema Association
National Eczema Society
National Kidney Federation
National Osteoporosis Society
National Rheumatoid Arthritis Society
National Society for Epilepsy
National Youth Advocacy Service
NAZ Project
Parkinson's Disease Society
Patient Concern
Patient Information Forum (PiF)
Patients Association
Patients' panels
Positively Women
Primary Immunodeficiency Association
Prison Reform Trust
Privacy International
Race for Health

Rethink
Sainsbury Centre for Mental Health
SANE
SCOPE
Self-help Nottingham
Shingles Support Society
Sickle Cell Society
Skin Care Campaign
Stonewall
Stroke Association
Telangiectasia Self Help Group
Terrance Higgins Trust
The Afiya-Trust
The BigOptOut
The Consumer Association
The Howard League for Penal Reform
The Inter Faith Network for the UK
The NO2ID Campaign
The Patient's Association
The Princess Royal Trust for Carers
The Psoriasis Association
The Salvation Army
The Scleroderma Society

The Sick Children's Trust
Tuberous Sclerosis Association
Vasculitis Trust
War On Want
Women's Health Concern
Women's Institute
Professionals
ABHI
ABPI
Academy of Medical Sciences
All Trust Chief Executives/ Directors of R&D, Directors of Clinical Audit/ Directors of IT
AREC
Association of Medical Research Charities
Association of Medical Royal Colleges
BCS ASSIST
Biobank
BioIndustry UK (BIA)
BMA
British Association of Sexual Health and HIV (BASHH)
British HIV Association (BHIVA)
Caldicott Guardians Council
Foundation for Information Policy Research (FIPR)
GMC

GTAC
Health care Commission
Human Fertilisation and Embryology Authority
Human Genetics Commission
Information Commissioners Office
Intellect
Kings Fund
MHRA
Monitor
MRC
National Information Governance Board
National Institute for Health Research (NIHR)
NICE
NPSA
NRES
Nuffield Foundation for Bioethics
Open Rights Group
PACC (Professional Association Clinical Coders)
PIAG
Pituitary Foundation
Primary Health Care Specialist Group
R&D Forum
RC General Practice

RC Midwives
RC Nursing
RC Obstetricians & Gynaecologists
RC Paediatrics & Child Health
RC Pathologists
RC Physicians
RC Psychiatrists
RC Radiologists
RC Surgeons of England
Research Councils UK
Royal Statistical Society
Royal Statistical Society
Service User Research Group for England (SURGE)
The Institute of Clinical Research
The Royal Academy of Engineering
UK Chapter of the International League against Epilepsy
UK Clinical Research Collaboration (UKCRC)
UK Clinical Research Network
UK Council for Health Informatics Professions (UKCHIP)
UK Mental Health Research Network
University Research Ethics Committees
Wellcome