Form to respond to BCS Response to NHS Connection for Health’s Consultation on Additional Uses of Patient Data

THIS FORM HAS BEEN MODIFIED FROM THE NHS CONNECTING FOR HEALTH WEBSITE BY REMOVING THE FIRST SEVEN QUESTIONS WHICH RELATE TO PERSONAL INFORMATION ABOUT THE RESPONDENT.

PLEASE COMPLETE THIS QUESTIONNAIRE. BCS WILL COLLATE THE INPUT RECEIVED FROM ITS MEMBERS TO ENABLE A COLLECTIVE BCS RESPONSE.

All completed questionnaires to Liz Long at BCS by Wednesday 19 November please.

Purpose

NHS is 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.

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

Completing the survey

The survey sets the scene so that you can give the NHS 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.

**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.

**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.

1. **Should anonymised data in ‘sealed envelopes’ be used for additional purposes if it is anonymised?**
   - □ Yes – Go to question 3
   - □ Yes, but only with the consent of the patient – Go to question 2
   - □ No, never – Go to question 3
   - □ I don’t know – Go to question 3

2. **If people should be asked for their consent to share anonymised data in a ‘sealed envelope’, when should they be asked?**
   - □ Every time anyone wants to use it
   - □ Just once to cover all uses
   - □ Only in specific circumstances – please explain below
3. Do you have any concerns or comments about the use of data held in sealed envelopes for research or other purposes apart from care?

4. 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?

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?

5. Should linked anonymised data in ‘sealed envelopes’ be used for purposes other than care?

☐ Yes – Go to question 7
☐ Yes, but only with the consent of the patient – Go to question 6
☐ No, never – Go to question 7
☐ I don’t know – Go to question 7

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

☐ Every time anyone wants to use it
☐ Just once to cover all uses
☐ Only in specific circumstances – please explain below

☐ Never asked
☐ Don’t know

7. 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?

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.

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

☐ Yes always – Got to Question 10

☐ Yes but only if a group like PIAG review the research first – Go to Question 10

☐ Probably but it depends on the type of research or who the researcher is – please explain - Go to Question 10
No, never – Go to Question 9
Don't know – Go to Question 10

9. If people should be asked for their consent to share identifiable data, when should they be asked?
- Every time anyone wants to use it
- Just once to cover all uses
- People should be allowed to specify that it is only used in certain circumstances e.g. for particular kinds of research – please explain below

Don't know

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

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.

11. 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, without seeking PIAG support
☐ Yes, but only with PIAG support it
☐ It depends on who the researcher is – please explain

☐ It depends on what the research is about – please explain

☐ No never
☐ Don’t know

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

☐ Yes possible for all types of research
☐ Yes possible but only for certain types of research or researchers – please explain

☐ No
☐ Don’t know

13. 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?
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.

14. Do you agree that the idea of an ‘Information Custodian’ is a useful one?

☐ Very useful
☐ Quite useful
☐ Not very useful
☐ Not at all useful
☐ Don’t know
Please explain your answer

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

15. Are there any other tasks that you would like the Information Custodian to do? Please write in:
16. Have you any concerns or comments about the use of an 'Information Custodian'?
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**

<table>
<thead>
<tr>
<th>Title:</th>
<th>Mrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name (s):</td>
<td>Pamela Anne</td>
</tr>
<tr>
<td>Last Name:</td>
<td>Smith</td>
</tr>
<tr>
<td>Address1:</td>
<td>52 Paradise Square</td>
</tr>
<tr>
<td>Address2:</td>
<td>Suburbia</td>
</tr>
<tr>
<td>Town:</td>
<td>Mooretown</td>
</tr>
<tr>
<td>County:</td>
<td>Moorshire</td>
</tr>
<tr>
<td>Post Code:</td>
<td>MN37 6AJ</td>
</tr>
<tr>
<td>Home telephone no:</td>
<td>0932 56478 9838</td>
</tr>
</tbody>
</table>

**Further Details:**

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

**Medical History**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Start date</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes Type 1</td>
<td>Since 1992</td>
<td>3 monthly checks</td>
</tr>
<tr>
<td>Influenza</td>
<td>30 Jan 1997</td>
<td></td>
</tr>
<tr>
<td>Urinary Tract Infection</td>
<td>16 Nov 1999</td>
<td></td>
</tr>
<tr>
<td>Urinary Tract Infection</td>
<td>20 July 2001</td>
<td></td>
</tr>
<tr>
<td>Acute back pain</td>
<td>3 March 2003</td>
<td></td>
</tr>
<tr>
<td>Chest Infection</td>
<td>10 Feb 2004</td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>14 Nov 2007</td>
<td>3 monthly checks</td>
</tr>
</tbody>
</table>

**Current Prescriptions:**

- Insulin
- Fluoxetine

**Surgery:**

- Tonsillectomy | 1968
- Wisdom Teeth Extraction | 23 March 1974

**Allergies:**

- Ibuprofen
- Penicillin

**NHS Reference Number:** ABCD12345678
Example of ‘Anonymised’ patient record

**GP Summary Patient Record**

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<tbody>
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</tr>
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<td>Address1:</td>
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<tr>
<td>Address2:</td>
<td></td>
</tr>
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</tr>
<tr>
<td>County:</td>
<td>Moorshire</td>
</tr>
<tr>
<td>Post Code:</td>
<td>MN37</td>
</tr>
<tr>
<td>Home telephone no:</td>
<td></td>
</tr>
</tbody>
</table>

**Further Details:**

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

**NHS Reference Number:**

<table>
<thead>
<tr>
<th>Medical History</th>
<th>Start date</th>
<th>Follow-up</th>
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<tbody>
<tr>
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<td>Since 1992</td>
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**Current Prescriptions:**

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<th>Pharmacy Item</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Insulin</td>
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<tr>
<td>Fluoxetine</td>
<td></td>
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</table>

**Surgery:**

<table>
<thead>
<tr>
<th>Surgery Type</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tonsillectomy</td>
<td>1968</td>
</tr>
<tr>
<td>Wisdom Teeth Extraction</td>
<td>23 March 1974</td>
</tr>
</tbody>
</table>
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 | 
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