

## **FREQUENTLY ASKED QUESTIONS ABOUT THE CANCER REGISTRATION PATIENT INFORMATION LEAFLET**

### **INTRODUCTION**

The Frequently Asked Questions (FAQs) are based on issues raised by patients and carers during the formal testing and piloting of the new patient information leaflet. They are intended to be useful to patients who, having read the leaflet, would like more information about the cancer registration scheme. They are also intended to provide additional background information for health professionals as an aid to dealing with any issues raised by patients.

*If you wish to contact the regional cancer registry covering your local area go to Question 12.*

### **1. The leaflet states that cancer registration is ‘allowed by law’. What is the legal basis for the national cancer registration scheme?**

Cancer registries for many decades operated on the principle of implied consent. This was in line with the contemporary NHS guidance on confidentiality. It was assumed that patients were willing for information collected about their illness and treatment to be used for legitimate purposes other than direct patient care. The implementation of the Data Protection Act (1998) and the publication of guidance from the General Medical Council in 2000, however, raised concerns about the validity of a system based on implied consent and highlighted the need to have a clear legal basis for the cancer registration system if it was to continue without explicit consent from individual patients.

The law that now covers the operation of the national cancer registration scheme in England and Wales is the Health and Social Care Act 2001. Section 60 of the Health and Social Care Act 2001 gives the Secretary of State for Health the power 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 suffice. It is intended largely as a temporary measure whilst consent or anonymisation procedures are developed, and this is reinforced by the need to review each use of the power annually.

In 2002 the United Kingdom Association of Cancer Registries sought, and obtained, approval under Section 60 (Regulation 2) to continue to use patient-identifiable data for cancer registration. This was approved by Parliament on 23rd May 2002 and came into effect on 1st June 2002.

Specifically, Regulation 2 makes provision for "the processing of confidential patient information in connection with the construction and maintenance of databases by bodies (known as "cancer registries") which undertake the surveillance of health and disease of patients referred for the diagnosis or treatment of neoplasia" [cancer]

Under the Act, a new independent body known as the Patient Information Advisory Group (PIAG) was established:

- To advise the Secretary of State for Health on regulations which should be made under Section 60 of the Health & Social Care Act
- To advise the Secretary of State as required on the use of patient information.

PIAG's role is to scrutinise carefully applications to use patient identifiable information made under Section 60 and to make recommendations where the use of the information requires Regulations to be laid before parliament or to approve applications, on behalf of the Secretary of State for Health, where the use of the information is limited to certain categories. PIAG also undertakes an annual review of each successful application to check whether the requirement to use identifiable data without consent is still valid.

*For further information see:*

[www.advisorybodies.doh.gov.uk/piag/Index.htm](http://www.advisorybodies.doh.gov.uk/piag/Index.htm)

## **2. The national cancer registration scheme has been established for more than 50 years. Why is a patient information leaflet being distributed now for the first time?**

In the past, it was assumed that there was a sufficiently strong public interest justification to use health information for purposes other than direct patient care without consent. With the Data Protection Act, it was clear that there is a responsibility to inform patients about specific uses of health information for purposes such as cancer registration. Cancer Registries have taken responsibility for producing a standard national leaflet explaining the cancer registration scheme and for working with cancer networks and the Department of Health to ensure that in future the leaflet is made available to all cancer patients.

At the first annual review of the Section 60 regulation covering cancer registration (see Question 1 for an explanation of what this means), the Patient Information Advisory Group (PIAG) reinforced the requirement for cancer registries to develop a communication policy to inform patients of their work, to advise them that registration is automatic following a cancer diagnosis, and to describe what personal information will be held and how it will be used. It requested that any information for patients should be tested with patient groups. During 2004, the leaflet has been tested with small groups of cancer patients and parents of children with cancer and with some representatives of national cancer patient groups. The leaflet has also been checked by the Plain English Campaign and the Centre for Health Information Quality (CHIQ) to ensure it can be understood by the average person. The leaflet is now ready for use and is being rolled out across the country.

## **3. What information is collected by registries?**

A wide range of information is collected, in keeping with the many uses described in the answer to **Question 8**. This includes the name, address, gender, date of birth, and NHS number of the patient, the type and location of the cancer, how advanced the cancer is, and the treatment received by the patient.

#### **4. How is the information collected?**

Unlike the system for certain communicable diseases, the registration process for cancer is not usually based on notifications from individual clinicians. Instead, cancer registries receive routine (often electronic) notifications from a variety of sources. These sources include district general hospitals, cancer centres, hospices, private hospitals, cancer screening programmes, other cancer registers, primary care, nursing homes and death certificates. Data are frequently received from several sources within an individual institution (e.g. pathology departments, medical records and radiotherapy databases). Increasingly the main sources of data for cancer registries are computerised hospital systems within pathology, oncology and other departments.

#### **5. Why is it necessary to collect identifiable information?**

There are five main reasons why, at present, it is necessary to collect information that identifies patients.

- Patients often attend more than one hospital. It is important to know that a cancer reported from a number of different hospitals relates, in fact, to the same person, otherwise registrations would be duplicated and cancer incidence rates would appear to be misleadingly high.
- An important indicator of the effectiveness of cancer services is the percentage of patients who survive their cancer. It would not be possible to link a patient's date of death to their cancer records without identifying information.
- People are often concerned that there might be a high risk of cancer in their locality. These risks cannot be investigated properly without knowing where patients with cancer live (based on postcode of residence).
- People are often worried that their family history may put them at high risk of cancer. An accurate family history is crucial if these individuals are to be offered appropriate advice. The cancer registry is often asked by clinical geneticists to confirm the details of a cancer diagnosis in a relative of someone attending their clinic. In the case of living relatives, this information is only released with the written informed consent of the relative concerned. Often, especially when medical records have been destroyed, the cancer registry is the only available source of such information.
- Occasionally, a previously unforeseen, significant late effect of therapy comes to light many years or even decades after that treatment was in widespread use. In these circumstances, it will be necessary, using all available information sources including the cancer registry, to try and trace all patients who might be at risk, so that they can be informed and counselled about possible interventions to reduce their risk.

## **6. Why can't registries use the NHS number instead of name and address?**

Cancer registries do use the NHS number to link records whenever possible. Although the NHS number has almost 100% coverage in England and Wales, not everyone's number can be traced and it still does not appear on every document produced in hospitals, e.g. pathology or radiology reports. Some patients might not therefore be registered, resulting in incomplete statistics. The NHS number consists of 10 digits and can very easily be mis-transcribed, which would lead to inaccurate data being recorded, possible duplication and the inability to link information to the correct patient. The use of the NHS number should improve over the next few years as it becomes more widely used to link records across the NHS as part of the work being undertaken by NHS Connecting for Health (previously called the National Programme for Information Technology). This should allow a further reduction in the use of identifiers other than NHS number by cancer registries.

## **7. Under what circumstances do cancer registries release identifiable data?**

The UK Association of Cancer Registries has produced a set of guidelines governing the release of data to outside parties, which has been approved by the Patient Information Advisory Group (PIAG). Identifiable data are shared between cancer registries and can be released to organisations (hospitals, primary care trusts and cancer networks) and individuals (doctors) providing care for those patients. They are only released to bona fide medical researchers who can justify the use of identifiable data and who have made application to, and been approved by the relevant Medical Research Ethics Committee and been granted Section 60 support through PIAG.

The UK Association of Cancer Registries confidentiality guidelines can be found at [www.ukacr.org](http://www.ukacr.org)

## **8. What is the information from cancer registries used for?**

Cancer registries undertake a range of public health surveillance and health protection functions. The main functions of cancer registries are :

- monitoring trends in cancer incidence, prevalence and survival over time and between different areas and social groups
- evaluating the effectiveness of cancer prevention and screening programmes  
For example, population based data are required to monitor the effectiveness of the existing national screening programmes for breast and cervical cancer and to inform the design of new programmes, e.g. screening for colorectal and ovarian cancer
- evaluating the quality and outcomes of cancer care by providing comparative data about treatment patterns and outcomes
- evaluating the impact of environmental and social factors on cancer risk. For example, cancer registry data are used to investigate possible cancer risks in relation to power lines, landfill sites and mobile phones.

- investigating differences in cancer incidence, survival and access to treatment between social classes and thus contributing to programmes aimed at reducing health inequalities
- supporting investigations into the causes of cancer
- providing information in support of cancer genetic counselling services for individuals and families at higher risk of developing cancer.

### **9. What are the benefits of the national cancer registration scheme?**

This is best summarised by listing some examples of what we know as a result of the work of cancer registries and what we will not know in future if cancer registration data become unreliable.

#### **What we know as a result of information obtained from cancer registration:**

- mesothelioma is caused by exposure to asbestos
- skin melanoma rates have been increasing year on year
- lymphoma and oral cancer rates are higher in ethnic minorities
- there is wide variation in how cancer is treated around the country
- cancer survival for patients living in poor areas is lower than for those living in rich areas
- cancer survival is lower in the UK than in Europe for most cancers
- cancer survival in children has improved dramatically over the last 30 years.

#### **What we may not know in future if cancer registration becomes unreliable:**

- how many cancers occur each year, and which are the most common
- whether cancer rates in the UK are increasing or decreasing
- if cancer incidence rates in the UK are higher or lower than in other countries
- if cancer survival rates in the UK have caught up with other European countries
- if inequalities in cancer treatment or survival between rich and poor have been reduced
- if cancer screening programmes are effective
- if people living near landfill sites or power lines have an increased cancer risk
- whether some late deaths in childhood cancer survivors are related to earlier treatments
- if the risk of developing certain cancers is higher in some occupational groups.

### **10. Can patients opt out of the national cancer registration scheme?**

Patients have the absolute right to opt out of the cancer registration scheme if they wish to do so. There are several things that must be understood when taking this option.

Ideally this would be achieved by the flagging of *all* their cancer-related records on *all* computer (and manual) systems feeding the cancer registry to prevent any records from being sent to the registry once the patient's objection was recorded. In practice, it is not currently possible to do this because of the limitations of hospital computer systems.

Currently, the most viable alternative is for the cancer registry to retain a record of the person's identifying details (the NHS number should be sufficient) without any clinical details attached so that any relevant records held by the cancer registry or received at a later date can be deleted. This arrangement and the reasons for it must be explained to the patient and, assuming they agree, their identifying details should be supplied to the cancer registry.

Some patients might be willing to have their details recorded on the cancer register and used to contribute to local and national statistics about cancer and for other purposes including research that does not involve patient contact. They might wish only to opt out of the possibility of being included in any research projects involving direct contact with patients. If this is the case, the regional registry will flag the patient's cancer registration records to ensure that their details would never be released to researchers for any research project involving patient contact.

However, if a patient wishes to have their entire record deleted, this wish must be respected. In such cases it **must** be made absolutely clear to the patient that without retaining their NHS number in the registry, the risk of re-registration from other sources is highly probable.

### **11. Are there any implications if a patient chooses to opt out of the cancer registration scheme?**

Patients have the right to be informed about the processing and uses of their information, and the right to object to their information being used in certain circumstances. When a patient expresses a wish to "opt out" of cancer registration, it is important that they understand what the cancer registry is, what information is collected, and what the information is used for. It is important for patients to be fully informed of the potential consequences of their "opting out" before they make this choice. It must also be made clear, however, that this will not affect their treatment and care.

For example, the decision to "opt out" may have

- implications for them personally – for example, it may not be possible to identify them as being at risk in future patient notification exercises.
- implications for their descendants – who may be deprived of complete information on their family history of cancer, leading to an inaccurate assessment of their risk, and the possibility of inappropriate management.
- implications for society – since the more people who choose to "opt out" of having their information included, the less useful the information becomes (for example, in the context of investigating a possible cluster of cancer, or identifying a problem with cervical screening or cancer treatment services).

It is also important to bear in mind that the use of cancer registry data to support genetic counselling and patient notification exercises is a relatively recent development that was not anticipated 15 years ago. It is not possible to predict other future potential uses of the data that might also place at a disadvantage patients who choose to “opt out”. While it is important to consider the potential disadvantages to the patient (and society) of “opting out”, patients should not feel pressured into agreeing to registration.

**12. If a patient or health professional wants more information about how the cancer registration scheme works in their local area or has any concerns they would like to discuss, whom do they contact?**

If a patient or health professional would like to know more about the cancer registration scheme or would like to discuss any concerns with their regional cancer registry, the appropriate registry can be identified by selecting either the hospital of treatment or typing in the postcode for the patient’s place of residence using the Registry Finder at the end of this section

If a patient has been treated in more than one hospital and the hospitals are in areas covered by different registries or if the patient lives in an area covered by one registry but was treated in a hospital covered by another, the patient or health professional need only contact one (either one) of the registries. The registries have undertaken to communicate with each other about any cross-over issues and to ensure that a patient wishing to opt out of the cancer registration scheme only has to deal with one body.

*Registry Finder*

**13. If a patient wants to opt out of the cancer registration scheme, what do they have to do?**

If a patient wishes to opt out of the cancer registration scheme they should contact the Director of the Cancer Registry for their local area or ask their doctor to do this on their behalf. The contact details for the regional cancer registries are shown in the response to **Question 12**.