

Registry Information Booklet



The Cystic Fibrosis Registry of Ireland (CFRI)
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Cystic Fibrosis

Cystic fibrosis is a recessive genetic condition which requires a multi-disciplinary medical approach to maximise the length and quality of life of those affected. Approximately 30-40 children with cystic fibrosis are born every year in Ireland. Because the genetic mutation which leads to cystic fibrosis is present in one person in 20, it is a very common and widespread trait. Thus, children with CF may be found living in any part of the country. At present, there are approximately 1,100 people with cystic fibrosis living in Ireland.

Cystic Fibrosis affects many bodily functions such as breathing, digestion, and reproduction. This lifelong condition usually becomes more severe with age and can affect both males and females.

The symptoms and severity of cystic fibrosis differ from person to person. The majority of people have both respiratory and digestive problems, while some may have only respiratory infections.

To date, there is no cure for cystic fibrosis. Life expectancy was very low 20 years ago, but it has increased steadily and now the total CF population will soon be dominated by those over the age of 18. Better treatment strategies help to improve the length and quality of life of people with CF by controlling their symptoms.

Questions and Answers

How to use this booklet



The blue text on the right hand page explains the Cystic Fibrosis Registry of Ireland.

Questions and Answers in plum colour are on the left hand page and relate to the sections on the right side.

What is a Registry?

Recent medical history in other countries shows that the overall condition of cystic fibrosis patients improves when CF specialist doctors share successful treatments with each other. Many countries have created central databases (something like electronic filing cabinets) where information on all CF patients is kept.

Doctors from different regions of a country submit medical information on their own patients to the central computer. They can then request reports that show the results of treatments on other doctors' patients. They are not able to see the other patients names or addresses, but they are able to see, for example, which antibiotic has been useful for treating a particular infection.

This type of database is often called a REGISTRY.

When information on treatments is stored in a computer system like this, then a doctor can ask the computer:

*“What antibiotics are used to treat
pseudomonas infections?”*

In the case of the Irish CF Registry, a doctor will be able log onto the Registry (with his secret password or PIN number) and find out how many patients have been successfully treated for *pseudomonas* in Ireland.

IMPORTANT: *It is important to note that when information is extracted from the Registry, it is NOT connected with anyone's name. The doctor will only be able to see how many patients responded to each treatment. He will not see their names.*

How will the information be collected and put into the computer system?

Your doctor or CF Nurse Specialist will talk to you about the Registry and ask you to sign a Consent Form. Once this happens, a copy of the signed Consent Form will be sent to the Registry Director, who will then go to the hospital clinic that you attend.

S/he will read your medical chart at the hospital and record the information from the chart into the computer system. This will happen every year after you are enrolled.

How will the information be used?

Each consultant will be able to see his own patients' records and these will all be on one system, so s/he will be able to get summaries of his/her practice over the last 12 months. For instance, s/he may want to know how many patients were treated as in-patients in the last year. S/he may also ask, 'what types of infections did my patients suffer from?' The answers will be found in the Registry as well as what antibiotics were used to treat those infections.



General Information about the Irish Cystic Fibrosis Registry

The CF Registry is a medical research information computer system. This system will be available to consultant doctors through the internet. Security issues concerning the system are discussed later in this booklet.

The purpose of the Registry is to keep all the medical records of each patient in a central place (computer). By doing that we can quickly find out the number of patients with cystic fibrosis in Ireland; how many are born with CF each year, and what medications each patient is taking. That information will help in planning for necessary hospital resources such as doctors, nurses and beds. This is one way where the Registry can support cystic fibrosis patients and their families throughout the country.

The information that is recorded will be taken from your medical chart in the hospital. There will not be any additional medical information in the Registry that is not in your medical chart.

There may be additional social information that is not in your medical chart that you will be asked. The answers to the social questions will help in planning educational resources that are specific for cystic fibrosis patients.

The Registry will not recommend any drug treatments or other treatments. The Registry only records what treatments have been given that were recommended by your doctors, nurses, physiotherapists, or dieticians.

There are NO additional procedures that will be recommended by the Registry. The doctor will continue to make the best decisions s/he can, as s/he does now. What will be improved is the information that is available to see what other doctors are prescribing and whether those medications work.

There will be no extra time requirement from the patient. One will continue to attend the clinic as usual.

All of the information collected will be used to improve the health of cystic fibrosis patients.

Who will participate in the CF Registry?

It is hoped that all patients with cystic fibrosis living in Ireland will participate in the Registry.

The more people that participate, the better the quality of the information that will come out of the Registry.

If I attend both a Specialist CF Centre and a regional centre, will I have 2 sets of information in the Registry?

No. Each person will have only one set of information in the Registry. Typically, the information forms will be filled in once a year at the Specialist CF Centre. The forms will be collected from the Specialist Centre and added to the Registry by the Director. This information will be available to another consultant if the patient attends that consultant, but in a “read-only” format.

Is every hospital in Ireland that treats CF patients taking part in the Registry?

It is hoped that every hospital that treats CF patients will take part. However, each hospital must approve of the Registry through their Ethics Committee, before taking part in the Registry.

Do individual hospitals have the option to not take part?

Yes. An individual hospital’s Ethics Committee may decide not to take part. To date, all hospitals specialising in CF treatment have approved of the Registry.

Who is responsible for the Registry to ensure that it is not misused?

The Registry Director is responsible for the creation and maintenance of the Registry. S/he is registered with the Data Protection Commission as a Data Controller. This ensures that only approved researchers can gain access to the Registry information and that patients have access to their data on request. These rights are protected by the Data Protection Act, 1988.

Aims & Objectives of the Registry

It is the aim of the Registry to enrol all patients with cystic fibrosis onto the database.

It is most important that registration is complete, accurate, timely and confidential.

The CF Registry hopes to:

- Collect information from patients' medical charts;**
- Use the information in the best interest of CF patients;**
- Provide information on long-term outcomes of CF patients;**
- Provide each consultant with information summaries of their own patients.**

Description of the Registry

The hospitals that participate will be assured that the legal and ethical aspects of gathering personal information have been addressed.

All participating hospitals have approved the Registry through their Ethics Committees. This is to protect the confidentiality of each patient who is enrolled. The consent forms that are used have been approved by each hospital.

The security of the Registry's system and premises will be assured at all times.

Every year an independent inspection will be done on the Registry. This is to make sure that all the information is accurate and confidential. This will be overseen by the Registry Committee, but will be done by independent experts.

Does the Data Protection Act allow me access to my information on the CF Registry?

The Data Protection Act 1988 guarantees individuals the right to a printed copy of their information if it is kept as a computerised record. Anyone who is enrolled on the CF Registry may apply to the Registry Director for a copy of their own information.

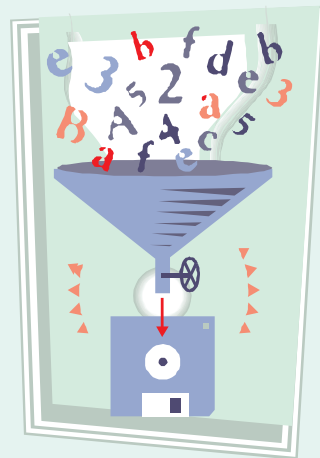
There are a very small number of circumstances outlined in Section 5 of the Data Protection Act which may limit your right to your computer records, but this is only where your health or well-being would be affected if you saw the information.

The regulations also suggest that a person who is not a health professional should not disclose health information without first consulting the individual's own doctor.

Thus, it is preferable that the Director gives a copy of your Registry information to your doctor (or any doctor of your choice) so that s/he will put the information into context for you during a consultation.

What kind of information will be stored in the Registry about each patient?

There will be two sections of information stored about each patient. The first section concerns your diagnosis: when CF was diagnosed and how. For example, it may have been at birth or shortly afterwards, or it may have been when you were older and suffered from digestive or respiratory problems. The second section of information will be an annual update. This will cover all the infections and treatments (including vaccinations) given to you over the last twelve months



Description, cont'd

Each patient may have access to their own Registry records. This is slightly different to hospital procedures that exist at present, because the Registry information will be kept on computer. More information on this subject is available through the Data Protection Commission (address: Block 4, Irish Life Centre, Talbot Street, Dublin 1; telephone: 01 874 8544). They also have a very informative web site: www.dataprivacy.ie

Each CF consultant will be able to see the medical records of his/her patients *ONLY*.

Personal records (for example, name, address and birth date) will only be available to a patient's medical consultant or the Registry Director. No CFAI (Cystic Fibrosis Association of Ireland) board member, CFAI staff member, or any agent of CFAI will have access to personal details or medical records that are recorded in the Registry.

The Registry Management Committee and the Registry Director will ensure at all times that only anonymous sections of the Registry will be available to approved researchers and doctors.

Patients' medical records will be collected from their hospital charts every year by Registry personnel and entered into the computer system.

The patient information will consist of two parts:

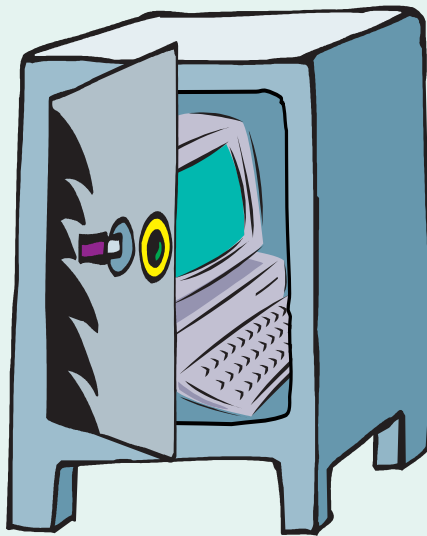
- (1) The first part is background information and diagnosis;**
- (2) The second part is a record of the patient's condition and medical treatment for the previous twelve months.**

If personal records are available to the consultant, does that include his team of junior doctors, CF nurses, physiotherapists, etc.?

This will be decided by each individual consultant. A special access “user name” and “password” will be assigned to each consultant taking part. He may submit a request to the Registry Management Committee that separate user names and passwords be assigned to named staff. However, when doctors rotate away from a CF service, their names will be withdrawn from the permitted usage list and their passwords cancelled.

If I am on the Registry before I turn 18 years of age, will I be asked about continuing on the Registry after I turn 18?

Yes. There will be a letter generated by the Registry computer which will direct your CF Centre to ask you to sign a Consent Form as an adult before your medical records can be submitted after you turn 18. No records will be entered into the system without a signed Consent Form on file in the Registry Office.



Security of the Database

As the nature of the data for the website is very sensitive, many security measures will be implemented.

- The server will be hosted (housed) in a secure building in Citywest Business Park. The building is alarmed and guarded 24 hr/day, 7days a week.
- The OS (operating system) installed on the machine requires usernames and passwords to access any data on the machine. These usernames and passwords will be issued to authorised personnel ONLY.
- The database is password protected on two levels.
- Security Certificate – The CF Registry will be issued a Security Certificate; this document is used by financial, government or any institution that wishes to protect its data from being intercepted. It is renewed each year.

Different people will require different levels of access to the database as described below:

- The Internet-Ireland Administrator will have access to the database (the ‘skeleton’), but not its contents (the ‘flesh’). They will be able to see the fields, e.g., **First name** **Last name** but not what is in the fields, such as **George** **Clinton**. To the Internet-Ireland Administrator, the ‘flesh’ in the case of **George** **Clinton** will appear as gibberish: **jd8ehe** **83jfa7adf**.
- The Registry Director will have access to the ‘flesh’, e.g., George Clinton, in order to make changes, such as a name change; but will not have access to change the ‘skeleton’. The Registry Director cannot add or delete fields.

The Registry Director will issue user names and passwords and can change these if a breach of security is reported to him/her (similar to notification of the bank if a PIN number is stolen).

- The medical consultant will be able to see the ‘flesh’ of his/her patients only. S/he will be blocked from seeing the personal details of all other patients.

What kind of “new information” might come to light because of the Registry? How will I find out about it?

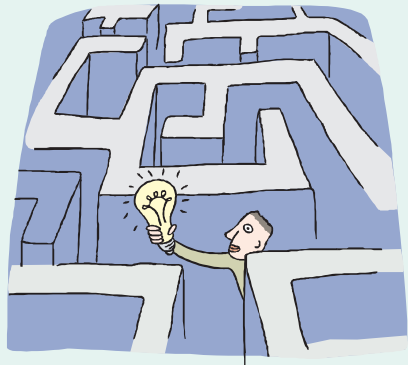
One possibility: It might be that new antibiotics will come onto the market in coming years. It is important that we know as soon as possible whether they are effective against the bacteria that affect CF patients. If all the CF patients who are taking a new product are in ‘one filing cabinet’, we have a better chance of knowing sooner if the new product is effective. As soon as an analysis takes place on the new product your doctor will be informed and s/he will tell you about the new information.

Who will be allowed into the system to retrieve information?

The Registry Director will be able to see everyone’s records in the system, because s/he will be putting the information into the system and ensuring that each consultant only sees their own patients’ information. No one other than the Registry Director or your doctor will be allowed to see anyone’s personal information. The CFAI may request reports from the Registry using the same process as any medical researcher. All information will be anonymous.

How will the Registry Management Committee decide on who can look at the information in the Registry?

If a medical researcher wishes to study the information on the registry, s/he must submit a research proposal to the Registry Management Committee. This committee will judge each proposal separately. Only anonymous data will be released for research projects. No personal data will ever be released to researchers. No funding for research projects is available through the Registry Management Committee.



Benefits of the Registry

After a few years doctors and scientists will be able to analyse the Registry to determine the long term outlook for Irish patients with cystic fibrosis.

They will also be able to compare treatments in Ireland with treatments in other countries. In the future patients may benefit from this medical research.

Such benefits include the possibility that one's condition may improve through assessment of current practices and that the Registry may assist in the development of new therapies.

Costs

There are NO costs attached to participation in the Cystic Fibrosis Registry of Ireland.

Confidentiality

Participation in the Registry will be treated as confidential and any personal records or results relating to the Registry shall not be disclosed to any third party other than one's consultant doctor or the Registry Director.

Information from the Registry may be used for the purposes of medical and/or social research only under strict conditions approved by the Registry Management Committee and that information will be anonymous at all times.

All information will be kept in accordance with guidelines issued by the Data Protection Commission and no personal information will be given to any person or agency at any time.

Will anyone outside of Ireland see my data?

None of your personal data will ever be disclosed to researchers either inside, or outside of Ireland.

However, there are plans to create a European CF Registry which will act as a research tool in the same way as the CF Registry of Ireland. This means that anonymous data from all European participant countries will be merged together in one large database. (For example, all CF children across Europe who are 5 years old might be compared for growth and infection measures.) There may also be international studies which will request data from the Irish CF Registry. The purpose of these studies is to find out if patients in some countries are receiving better treatment than other countries. This will eventually lead to best-practice guidelines so that more people will benefit from successful treatment.

The Registry Management Committee and the Data Protection Commission in Ireland will ensure that no personal data identifiers will be merged with information outside of this country.

What advantages are there for me if I participate in the Registry?

It has been shown in other countries that the overall care of CF patients improves once all their medical information is in one system (i.e., a Registry). Your treatment can be compared with many others (not just the patients in your own clinic) and this may reveal areas for improvement in your care.

What disadvantages are there for me if I do not participate in the Registry?

There are probably no obvious disadvantages for one single person to refuse to participate. It may be more useful to look at it from the other perspective: if everyone participates, everyone gains. Participation is voluntary however, and you may withdraw from the Registry at any time.



Voluntary Participation

Participation in the Registry is voluntary.

Refusal to participate in the Registry will involve no penalty or loss of benefits to which one is otherwise entitled.

Anyone may discontinue their participation in the Registry at any time without loss of benefits to which they are otherwise entitled. Everyone is entitled to receive a copy of their signed Consent Form.

Right to Withdraw from the Registry

Anyone enrolled in the Registry has the right to ask any questions concerning the Registry at any time.

An enrollee will be informed by his/her doctor(s) of any significant new information pertaining to his/her condition that arises from information contained in the Registry.

An enrollee has the right to withdraw from the Registry at any time.

If someone would like their information removed from the Registry, they will be given copies of the information that is removed from the Registry and assured by a computer specialist that the information has been taken from the Registry (computer system).

Registry Management Committee

Mrs. Linda Foley*, Director, CF Registry of Ireland
Professor N.G. McElvaney**, Beaumont Hospital and R.C.S.I.
Dr. Peter Greally, National Children's Hospital in Tallaght
Dr. Charles Gallagher, St. Vincent's University Hospital
Dr. Gerry Canny, OLHSC, Crumlin
Dr R. Tummaluru, Sligo General Hospital
Mr Godfrey Fletcher, CEO, CFAI
Mr. Martin Wickham, IT Director, ESAT, Member CFAI
Mr. Carl Rainey, Chairperson, CFAI
Ms. Gerardine Leen, CF Specialist Nurse NCH, Tallaght
Ms. Anne Marie Lyons, CF Specialist Nurse, Beaumont Hospital

* The Registry Director is registered as a 'Data Controller' with the Data Protection Commissioner (Data Protection Act, 1988).

** Professor McElvaney is Chairman of the Registry Management Committee.

Questions/Queries

If you have any questions, you may contact the following people:

My CF Consultant, Address & Phone no.

My CF Specialist Nurse(s), Address & Phone no.

Registry Director:

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