



CENTRALISED HEALTH-SECTOR DATABASE

QUESTIONS AND ANSWERS

Centralised Health-Sector Database

- → A centralised database is a collection of selected health data, derived from medical records, coded and stored in computerised form in one location.
- → The database is a tool for scientific research.
- → The database will be operated and financed by a private company, that has an exclusive licence for specified use of the data for a period of 12 years.
- → The company and individual health institutions and health workers will negotiate on the creation and use of the database.
- → Consent will not be sought from each individual for entry of data onto the database, but participation may easily be refused by giving notice to the Director of Health.
- → The database will be monitored by ethics committees, the Data Protection Commission and a specially-appointed monitoring committee.

Introduction

This booklet contains a number of questions which are often asked on the subject of the new Act on a Centralised Health-Sector Database (Act no. 138/1998), and related issues. No doubt these are not the only questions that people would like to ask. Some can be answered by reference to the Act itself, while others may require further explanation. The Ministry of Health and Social Security has appointed a monitoring committee, which will monitor all negotiation of contracts in connection with the database, and closely monitor all its operations, when they begin. By the provisions of the Act, entry of data into the database may not begin until six months after the

Act has been passed, or the middle of June 1999. The delay will in fact probably be longer. An interdisciplinary scientific ethics committee has yet to be appointed. This committee will consider all research projects to be carried out using the database, and ensure that the interests of participants in such studies are protected. Regulations on scientific/ethical monitoring have yet to be drawn up, and no negotiations have yet been initiated with health institutions on entry of data into the database. Various aspects thus remain unclear. Another booklet will be published later, containing more detailed information, as the dissemination of information on this subject, and public debate, must continue. It is clear that members of the public have time, at least until June 1999, to familiarise themselves with the subject and make up their minds.

1. What is a centralised database?

A centralised database is a collection of selected health data, derived from medical records and stored in computerised form in one location. The data will be coded, and protection by access limitations. They are not to be traceable to individuals (i.e. not personally identifiable), except by expending considerable funds and manpower, and subject to revocation of the operating licence, fines and imprisonment.

2. What is the purpose of the database?

The purpose is to make health data accessible for purposes of scientific research, especially in the field of research into hereditary disease, and epidemiological studies. Also to make data available for the development of new and better methods in improving standards of health, for prediction, diagnosis and treatment of disease, and to facilitate the assessment of effectiveness of the work of the health service. By means of the centralised database, it should be possible to gain knowledge which it would be far more difficult to acquire by other means.

3. What data will not be entered in the centralised database?

Many databases are already in existence in Iceland, containing a variety of health data, and many of these are used for, among other things, scientific studies. These databases will not automatically be included in the centralised database. Thus the Act does not apply to databanks compiled for scientific purposes by various scientists. This includes, for instance, the Cancer Society database, the database of the National Association for the Prevention of Heart Diseases, or data collected by health authorities on the operations of the health service and its clients.



4. What kind of data will go into the database?

No decision has yet been made on precisely what data will go into the database. These will probably include such information as diagnoses, surgical procedures, medication treatments and results of clinical tests (e.g. x-rays, blood tests, urine tests). It is improbable that the written notes in medical records will be included as such. Genetic data derived from biological samples previously donated for purposes of scientific study will not be entered into the database, except with the consent of the individual concerned (informed consent).

5. Will health data on individuals remain in their present locations?

Yes, all data will remain in individuals' health records, and health workers will make notes in the same way as at present. Computerisation of medical records at health centres and hospitals is in progress, and this will make data both more accessible, and more secure, than at present. The existence of the centralised database will make no difference to this.

6. How will data be entered into the database?

Health workers at each institution will carry out processing of data for entry into the database, on the basis of agreements to be negotiated between institutions or self-employed health workers on the one hand, and the licensee on the other. Data will be entered both from written (paper) documents and from computerised records, which will become more accessible as time goes by.

7. How will privacy be ensured?

Personal identification will be coded before the data are entered into the database, so that the licensee's staff work exclusively with data that should not be traceable to any individual. The coding will be one-way, so that the coding cannot be reversed. The coding will be under the supervision of the Data Protection Commission, which will carry out further coding, by those means that best ensure personal privacy. Linking of the data to other information is also subject to various provisions and protocols, which must meet with the approval of the Data Protection Commission.

8. Who will compile and operate the database?

Having received recommendations from qualified parties, the Minister of Health grants an operating licence to a specified party, in return for payment of a fee, and subject to certain conditions being met, which are specified in the Act. The licence is valid for a maximum of twelve years, after which period the ministry acquires all rights relating to the maintenance and operation of the database.



9. Will it be possible to link the centralised database with other databases?

Under the terms of the Act, provision is made that the database may be linked to a database of genealogical data. The licensee is to draw up protocols regarding this which meet the standards of the Data Protection Commission for ensuring personal privacy. Specific consent must be sought from individuals if data from prior genetic studies are to be used in a new study.

10. How will processing in the database be carried out?

In processing, it is important to ensure that the data cannot be traced to individuals. The licensee may not grant others access to the data on the database, and it is prohibited, and is to be impossible, to extract information on individuals.

11. Will the existence of the centralised database have any influence on the treatment which people receive in the health system?

No. People's access to health staff and health institutions will, of course, be unchanged, and access to medical records will be limited as before. It should be mentioned especially that only the Directorate of Health will have information on which individuals do not wish data about them to be included in the database. Personal information on these individuals will be coded at the Directorate of Health, and the data will be stopped and destroyed automatically before entering the database. Thus health workers will not be aware of the identity of those who refuse to be included.

12. How will the operation of the database, and research projects, be monitored?

A specially-appointed monitoring committee of three will ensure that the creation and operation of the database is consistent with the law. It will also monitor all enquiries submitted to the database, and the processing of them, and send the National Scientific Ethics Committee details of all enquiries and enquirers. The Data Protection Commission monitors the observation of confidentiality in keeping with the law. Finally, a special inter-disciplinary ethics committee will assess all research projects carried out within the licensee's company, and all enquiries submitted.

13. How can people ensure that data on them are entered into the database?

The Act provides that data on all those who do not refuse participation will be entered on the database, i.e. that "silence means consent" (assumed consent).



14. How can people refuse to have data on them entered in the database?

Notice must be submitted to the Director of Health on a special form. The form may be sent by post or fax, but not by e-mail as this does not include a signature. The receipt of such notice will be acknowledged. The forms have been distributed to health institutions, pharmacies, the State Social Security Institute, embassies, etc., it has been published as an advertisement in the press, and it appears on the homepage of the Director of Health (www.landlaeknir.is). The form provides options to exclude from the database data which are already in medical records, data that may at any time be recorded in medical records, or some specified data. More than one option may be chosen. It is desirable that one form be submitted for each individual who wishes to be excluded; the form may be photocopied. The Directorate of Health will take responsibility for ensuring that this decision is respected. The individual does not have to contact each institution and health worker he/she has consulted for health care. Parents and guardians decide on behalf of children and those who are not legally competent.

15. How will data on the deceased be handled?

In Iceland and elsewhere, there is a long-standing tradition of using data on deceased persons from medical records and tissue banks for scientific research. Such scientific studies, like others, require the approval of the ethics committee and Data Protection Commission where applicable. By the terms of the notes to the Act on the database, the law does not provide for people to be able to refuse permission for entry of data on their deceased parents or relatives into the database.

16. Can people who have previously agreed to have data on them entered in the database change their minds?

People can, naturally, change their minds at any time, and no explanation of this is required. If someone has agreed to be included in the database, and then changes his/her mind, and submits a form of refusal after the collection of data has begun, the collection of data on him/her will immediately cease. By the same token, those who have refused participation may change their minds and withdraw their refusal. This may be done in writing to the Directorate of Health.

Glossary

Non-personally identifiable data: data that cannot be traced to an individual except by considerable expense and manpower.

Biological sample: tissue (e.g. blood, semen, tissue biopsy) from a living being.



Genetic data: data from a biological sample, which show structure of genetic material, characteristic for each individual.

Genealogical data: data on the relationship between people, e.g. family trees, inc. those in computerised form.

Epidemiological studies: studies on the frequency and spread of disease.

Informed consent (for research): the acknowledgement by an individual (generally in writing) that he/she gives permission for participation in a certain study, or that information on him/her may be used, the individual having received and understood information on the purpose and practice of the study, the potential benefits and risks of participation in the study, and that he/she is free to refuse participation or cease participation at any time.

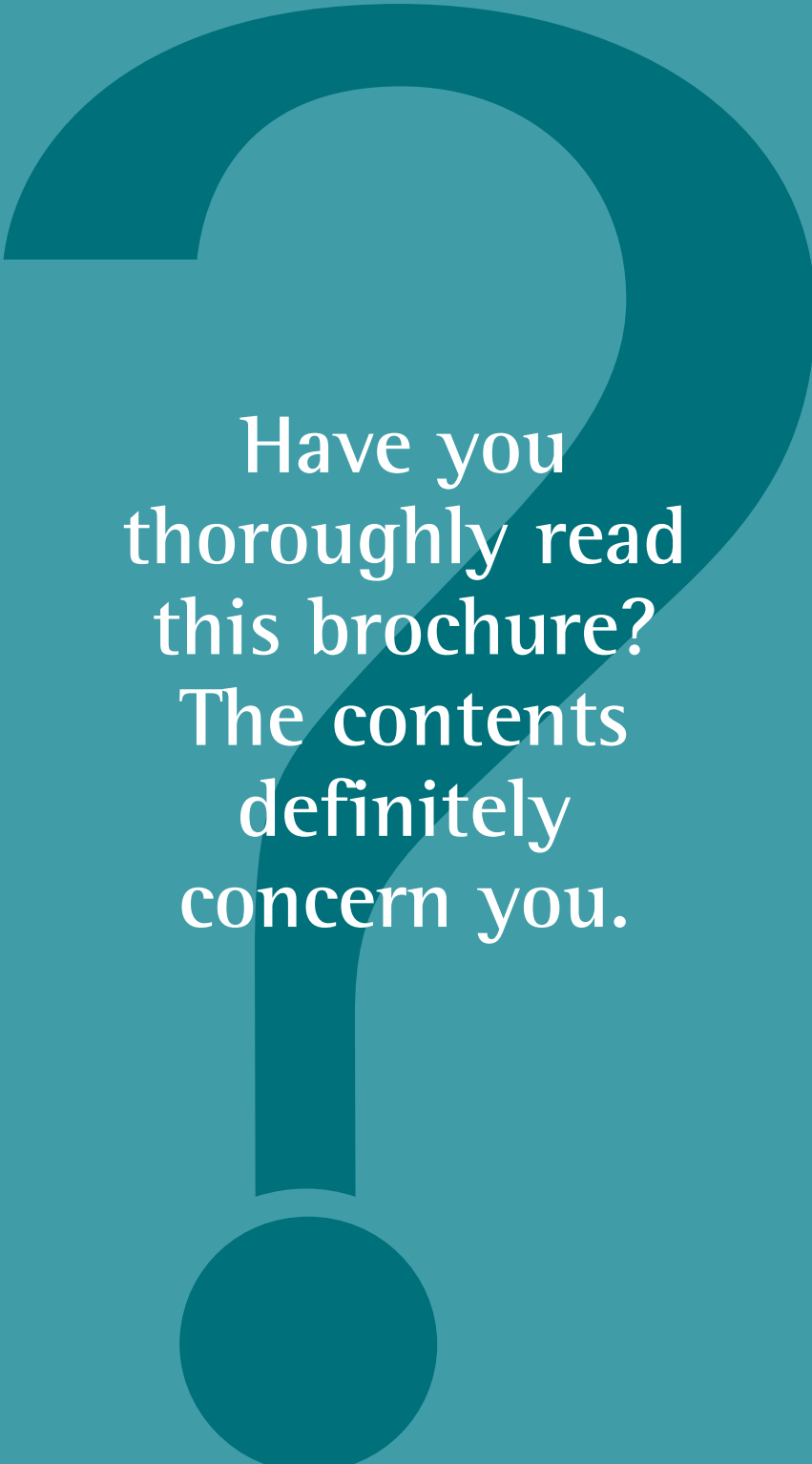
Presumed consent (for research): it is called presumed consent when an assumption is made that an individual consents to participation in a study if he/she does not declare that he/she does not consent, being aware of the study being carried out. There is no guarantee that the individual has familiarised him/herself with the matter. It should be simple to refuse participation.

Data Protection Commission: a commission appointed by the Minister of Justice to monitor the implementation of Act no. 121/1989 on the recording and handling of personal data.

National Scientific Ethics Committee: a committee which is to make an ethical assessment of scientific studies on human beings, operating under the terms of Regulation no. 449/1997, made on the basis of Act no. 74/1997 on the Rights of Patients.

Monitoring Committee: a committee appointed by the Minister of Health to monitor the creation and operation of the database, under the provisions of the Act on a Health-Sector Database no. 139/1998.

Interdisciplinary ethics committee: an ethics committee, comprising people from various different disciplines, under the terms of art. 12 of the Act on a Health-Sector Database no. 139/1998, which is to assess whether there are any scientific or ethical objections to studies planned within the licensee's company, and enquiries submitted to the database.



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thoroughly read
this brochure?
The contents
definitely
concern you.