Summary

Health Council of the Netherlands. The term for retention of medical records. The Hague: Health Council of the Netherlands, 2004; publication no. 2004/08.

The Medical Treatment Contracts Act (WGBO) states that patient data must be retained for ten years, or for as long after the expiry of this period as is necessary in order to provide a proper standard of care. The background to this stipulation is the central principle underlying European and national privacy legislation, namely that personal data should not be retained for longer than is necessary in order to fulfil the purpose for which they were collected. The converse of this provision in the WGBO is therefore that data that are more than ten years old *and* no longer required in order to provide a proper standard of care must be destroyed. This obligation to destroy data has been deferred under a transitional provision until 1 April 2005.

A widespread debate has arisen in recent years over the regulation of the retention period in the WGBO. Care providers and patient organizations are concerned that data are being lost that may subsequently once again prove to be of importance to the care of patients or their relatives. Researchers stress that exposure to a particular routine treatment may possibly, still after even ten years, prove to have late consequences that merit closer investigation. Moreover, the concern is growing progressively as the massive clearout of records over ten years old that is expected to happen before 1 April 2005 gets ever closer.

In an earlier investigation, the Health Council recommended a suspension of the policy of data destruction, which in some places is already under way, and an investigation of how optimum use can be made of the scope for longer retention that is offered in the Act itself. The Council also called for a fundamental analysis of the problem, ‘taking

into account current developments in the fields of care and research, the background to the present legislation and international aspects'.

In the summer of 2002 the President of the Health Council set up a Committee with the remit of performing that analysis and, in doing so, to also give consideration to the voice of the patient. The analysis was to culminate in a survey of possible solutions to the identified problems. This advisory report marks the realization of that remit. The Committee finds that the present regime leads to serious problems in various areas (namely care, research and relatives) that can only be resolved through a change in the law.

Legal context

A European Data Protection Directive (95/46/EC) has been in force since 1995 in an effort to harmonize legislation within the European Union in the area of personal data protection. In the Netherlands, that Directive has been implemented in the Personal Data Protection Act (WBP). The WGBO provides sector-specific regulations governing the management of personal data in the context of healthcare. The WBP and the WGBO are complementary.

According to the WGBO, care providers must include in the patient's medical records all data pertaining to his or her health and treatment that are necessary in order to provide the proper standard of care. Care providers should keep this data for as long as that is the case. Personal medical data must not, however, be unnecessarily retained. The invasion of personal privacy that is inevitable when embarking on a therapeutic relationship must be reduced to the minimum possible level. Retaining data for longer than is necessary not only conflicts with this principle; it also unnecessarily exposes the person concerned to risks associated with the transfer of his or her personal data.

The principle of 'purpose specification' means that personal data that are no longer needed for their original purpose must not be used for other purposes (and thus also not retained) without the consent of the concerned person. General privacy legislation does, in fact, leave some scope for retaining personal data for scientific research, even without consent. Owing to the duty of professional confidentiality, the WGBO is more stringent on this point and does not provide that scope. That Act does, however, include an exceptional provision that permits care providers to give personal medical data to scientific researchers under certain conditions, among them being the fact that the concerned person did not object.

The answer given in the WGBO to the question of how long the data contained in the patient's medical record should be retained is in two parts: 'ten years (…) or for as long after the expiry of this period as is reasonable in order to provide the proper standard of care'. According to the Explanatory Memorandum, those ten years must be

regarded as a ‘general minimum retention period’. Unless the patient him/herself requests that the data be destroyed earlier, the care provider must keep them for as long as is necessary in order to be able to provide him or her with a proper standard of care, with the minimum period being ten years. In practice, those ten years are, however, frequently interpreted as a maximum and the ‘or for as long after …’ as exceptional grounds. Thus the basic message inferred from the regulations is not ‘retain unless …, but ‘destroy unless …’.

Dutch law compared with other European countries

The Committee has sought to establish how the regulation of the term for retention of medical records in the WGBO compares with the relevant laws and regulations in other countries that, like the Netherlands, are bound by the European Data Protection Directive (Directive 95/46/EC), or else voluntarily comply with its provisions. The comparison includes Belgium, Germany, England, Finland, Norway, Spain and Sweden. Regulations vary markedly in this area, not least as far as the length of the terms for retention of medical records is concerned. There are longer periods than the ten years stipulated in the Netherlands, but also shorter ones. If, however, we consider all of the regulations governing the retention of medical records in the countries examined, then the term specified in the Dutch WGBO cannot be regarded as generous. In a number of countries, separate legislation is in place whereby medical data that are no longer required for patient care must, subject to certain conditions, be retained for scientific research purposes. In the Scandinavian countries, archival legislation plays an important role in this respect.

Problem areas

A survey undertaken by the Committee reveals that a retention period of ten years is, in many cases, too short. This is due in part to significant developments in the field of medicine that have become ever more prominent since the drafting of the legislation. Diseases that were previously fatal are now treatable, but this frequently means that people have to reckon with an increased, lifelong risk of relapse. A hereditary factor is being found to play a role in an increasing number of diseases and conditions. Members of the patient's family may also have an interest in the fact that his/her data are not destroyed after ten years. Furthermore, various correlations between previously experienced diseases or treatments and the possibility of health problems emerging later in life are more widely understood and taken into consideration. It is important – both for the research into these conditions and for the further care of patients who have been exposed to treatments that have been revealed to have late complications – that medical data should be

retained for (much) longer than ten years. The meant research also requires that retention does not stop after the death of the patient.

Longer retention within the present WGBO

Although longer retention periods can be discussed for specific areas of care in the interests of delivering the 'proper standard of care', ten years is too short to assess what data might still be needed in the future. Furthermore, consideration may then only be given to the interests of further care for the patient whose data are in question, and not also to the interests of medical research or the possible interests of (future) relatives.

However, where the proper care of the patient him/herself constitutes grounds for longer retention of records, there should not be any problem under the existing wording of the WGBO. This presupposes that it is possible and feasible in practice to distinguish data that, according to that criterion, do still need to be retained and data which do not. It has been proposed that the scientific associations should draw up guidelines for this situation. It seems unlikely, however, that these will be forthcoming before the expiry of the transitional provision on 1 April 2005.

Longer retention: scope for adaptation of the law

General privacy legislation leaves scope for any extension of the present retention period that may be required for the purpose for which medical data are collected, i.e. provision of a proper standard of care to the patient. This could still be a minimum period, with the possibility of supplementing it by issuing guidelines for data in specific areas of care. A longer retention period also means that medical data are available for that much longer for research, family interests and legal claims.

Some other adjustments to the WGBO are also conceivable within the framework of general privacy legislation. It could be prescribed that medical data must be retained if this would meet an important health need on the part of someone other than the patient. It is also conceivable that a patient might have a 'right to demand retention of medical records', complementarily to his/her right to demand destruction of data, which is already recognised in the Act. By virtue of that right to demand retention, the patient would be able to ensure that data whose retention period has expired and which are no longer required in order to provide a proper standard of care, are nonetheless retained. The patient may ask for this with a view to the possibility of himself or his relatives having a renewed need for those data in the future, or with a view to their importance for scientific research.

The separate statutory regulations governing the retention of medical data for scientific research that exist in certain other European countries are based on an exceptional

provision within the Data Protection Directive. This states that Member States may, for reasons of important public interest, formulate (by statute or decree) additional derogations from the prohibition on the processing of sensitive personal data. This is contingent upon the provision of appropriate safeguards to privacy. The WBP incorporates a similar provision. Finally, it is conceivable that the same exceptional provision could be invoked for what would be the most radical solution, namely the enshrinement in law of a very long general retention period (e.g. 100 years after the birth of the patient), taking into account not only what good care would require, but also the interests of both research and relatives. It would then be necessary to demonstrate the need for such a measure in the public interest.

Discussion

In so far as a longer retention period is necessary in order to offer patients a proper standard of care, it is not inconsistent with the basic principles of privacy protection. Additional measures may well be needed in order to combat the greater risk of data being misused and the consequences that might ensue. Furthermore, periodic clean-ups are required in order to avoid data overload. The Committee does not consider the higher costs that are inevitably associated with longer retention, even in the electronic era, as an argument for rejecting an extended retention period. These costs can be justified as being necessary in order to ensure the quality of care provision. The extension of the retention period must, however, be proportional. For example, the objective of providing the patient with a proper standard of care will not automatically necessitate lifelong retention of all his/her medical records.

According to the Committee, it is possible to justify separate rules governing retention of records for medical research – given the appropriate safeguards – on the grounds of the public's interest in a proper standard of healthcare and by acknowledging that the problems in this area cannot be conclusively resolved through less radical measures. These less radical measures include giving primacy to the voice of the patient, who would then be able to exercise his/her right to demand retention of records in order to ensure that data are retained for scientific research. The meant statutory regulation may be so construed as to allow that data retained for scientific research remain accessible for purposes of care (feedback option). The conditions for this would have to include the existence of an important health need for those data on the part of the patient or any of his relatives.

The concept of retaining hereditary data for the possible benefit of future relatives is at odds with the fundamental tenets of general privacy legislation. Here the Committee does, indeed, see an important role for the patient's voice. Current practice in the field of clinical genetics (i.e. the retention of hereditary data for three generations) could be

maintained through the patient's right to demand retention of records, albeit on the condition that the patient must then have declared himself in favour of this practice. An alternative would be the aforementioned feedback option. If data retained for scientific research remain accessible in the event of an important health need for those data on the part of the patient or any of his relatives, this would be a further way of safeguarding that future relatives will have access to those data if need arises. That same approach may also offer a solution with regard to the possible interests that (future) relatives might have in the retention of data whose hereditary nature is not discovered until after the retention period has expired.

Conclusions and recommendations

The Committee believes that a change in the law is required in order to create the scope for substantially longer retention of medical data. The new regime must provide a coherent response to all of the problems that have been identified in this advisory report. Although the Committee finds it conceivable that new scientific developments may over time give further backing to the aforementioned radical solution (consisting of a very long retention period in which all relevant interests are simultaneously accounted for), this is not what it recommends. According to the Committee, a regime that includes separate retention procedures for care, research and relatives will provide the presently best arguable balance between the interests of longer retention of records, on the one hand, and the fundamental principles of privacy protection and the patient's voice on the other. The Committee gives the following outline for this regime:

- There will be a longer retention period for the care of the patient. The Committee can envisage parallels being drawn with the 30-year period that is specified in new European and Dutch regulations setting quality and safety standards for human tissues. The new period is seen as a minimum term. Since it may be necessary to retain certain data for longer, there will still be a need to develop specific retention guidelines.
- There will be a statutory regulation governing retention for research purposes. In other words, personal medical data that are no longer required for the care of the patient will fall under a separate regime, whereby they can be retained (wherever possible in an indirectly traceable form and subject to certain conditions) for as long as is necessary for the purposes of medical research. This proposal requires further elaboration, with consideration needing to be given to such matters as the purpose of the registration, the period of retention, the selection of the data to be retained, the manner in which the data are retained, the data-protection measures to be taken, the conditions under which researchers may utilize the data, and the question of whether or not it is necessary to incorporate a feedback mechanism allowing that, under cer-

tain conditions, data retained for scientific research remain accessible for purposes of care.

- Supplementary provisions will be incorporated into the WGBO that make it possible to retain hereditary data for as long as is necessary in the interests of the family. This refers to the stipulation that medical data must be retained if someone other than the patient should have an important health need for these data and the explicit granting to patients of the right to prevent the destruction of their data (i.e. the right to demand retention). Furthermore, the interests of relatives may constitute grounds for considering the feedback option mentioned above.

The Committee calls for swift decision-making on its proposal for a new retention regime. It is essential that the distinct elements of which it is made up are evaluated in the context of the proposal as a whole.

Until such time as the necessary legislative changes have been implemented, it will be necessary to prevent (further) destruction of medical data. That can only be achieved by adapting the existing transitional provision contained in Section IV of the WGBO. Extending the transitional period by five years – i.e. until 1 April 2010 – will provide sufficient time for careful decision-making, but also make it clear that there is no room for further delay. The message of the revised provision must be that no medical data must be destroyed before that date. The Committee emphasizes that this adjustment of the transitional provision is urgently required.

The scientific associations would need to utilize the breathing space thus provided for developing guidelines, not only with a view to longer retention of data in specific areas of care, but also for the necessary periodic clean-ups of records.

The patient must be given a greater voice in the management of his or her data. This necessitates the provision of proper information, with consideration also needing to be given to the important role played by medical data and their retention in the provision of a proper standard of healthcare. The Committee envisages here a sharing of responsibility between the scientific associations, the patient organizations and the institutions.