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EC Proposal for Directive Can Destroy the Possibilities of Cancer Research

THE EC Commission has prepared a proposal for a directive regarding the protection of individuals in relation to the processing of personal data.

The proposal aims at establishing uniform regulations which at European level protect the fundamental rights of individuals by means of a high level of protection. The superior intentions of the proposal can only be sympathised with, but these intentions cannot reasonably be looked at separately. They should be looked at and weighted in close connection with other aspects, which are also of importance to individuals. This also applies to research into diseases, including epidemiological cancer research, and the prevention of diseases, which presupposes that causes and factors, which are known, contribute to the disease.

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Most alarming are the demands of the proposal for a directive for: informed consent of the data subject at the time of registration, informed consent of the data subject when communicating data to third parties, and data that cannot be processed for other purposes than those for which they were collected.

These demands will, to a wide extent, make register-based epidemiological research impossible. As an example it can be mentioned that informed consent will make it impossible to interpret stored data, as we do not know the criteria which form the basis of the recording of the data subject or the lack of same. This will make files incomplete, and reduce the value of research. Informed consent in connection with communicating data concerning health to third parties may have unintended effects on the data subject, who is informed by an existing register about a disease, which the person in question has not previously been informed about, therefore such information should always be given through the data subject's own physician. For deceased

persons such a rule is impossible to practice—and who should then be informed?

Most serious are, however, the restrictions concerning data which may only be used for the purpose for which they were collected. It is a fact that it is often an unforeseen combination of data from various data sources, which result in very important research achievements and which can be used for establishing the course of the disease and for the prevention of diseases. Within cancer epidemiological research, linkages between cancer files and information on occupational groups should be mentioned, as it has been possible to evaluate occupational exposure to carcinogenic factors or even the importance of the occupation for the development of cancer, or linkage between other files concerning diseases. The proposal for a directive suggests that "files concerning diseases" may be excluded from the scope of some of the provisions, but the limited possibilities of linkage with other "files concerning non-diseases" may be characterised as a disaster to research, and in the long run they will have unintended effects on both individuals and the public as a whole, who are then prevented from benefiting from the experiences of other cancer patients.

In connection with the discussions of the proposal for a directive which have taken place so far in a number of committees under the European Parliament, a considerable number of objections and amendments to the present proposal have been put forward.

The Association of European Cancer Leagues (ECL) has made a number of politicians, authorities and scientific committees at the national, as well as at the EC level, aware of the proposal for a directive and the very negative effects an implementation of the present proposal for a directive is bound to have on cancer research. These initiatives have received positive response.

Presently there are indications that the EC commission—after the European Parliament voiced its opinion on the proposal for a directive in December—will prepare a new and greatly revised directive in the course of February–April 1992.

Therefore, it is of the utmost importance that the near future sees broad and massive efforts through existing national and EC networks in order to influence the new version of the EC directive, so that research is excluded from the scope of the directive, or that any unavoidable provisions are based on reasonable and useful legislation such as the legislation which has been applied in the Nordic countries, including Denmark, over the last few years.

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Axillary Surgery in Breast Cancer—Is There Still a Debate?

IT IS PARADOXICAL that when the most extensive axillary surgery was performed there was no form of systemic therapy in use which could affect survival. Now that proven adjuvant treatments are available for both premenopausal and postmenopausal patients, many are missing out on the opportunity for cure or prolongation of life because of inadequate axillary surgery missing metastatic disease and increasing the risk of local relapse.

Consistent evidence shows that clinical evaluation of the axilla has low (60%) sensitivity and specificity [1, 2]. Furthermore, attempts to image the axilla radiographically, ultrasonographically or by lymphoscintigraphy have been unsuccessful [3]. Thus the pathologist is still the final judge, provided of course that the evidence of the surgical specimen is adequate.

This should not be seen as an argument between axillary sampling and axillary clearance. The function of node sampling is with minimal morbidity to obtain sufficient nodes for negativity to be confirmed. Thus, when carried out well, it has a specificity greater than 95% [4]. Those who have achieved these results do not regard sampling as an adequate treatment for the involved axilla. If axillary lymph node metastases are confirmed histologically (possibly by frozen section) the procedure may be converted to a clearance, or treated by axillary irradiation.

Unfortunately many surgeons do not know how to carry out this procedure because they were trained by consultants who carried out a total mastectomy and either left the axilla to its own devices, or alternatively gave indiscriminate radiation.

There are still a few surgeons who neither clear nor sample the axilla. This is unacceptable. Without this prognostic information systemic therapy may not be given when appropriate, and risk of local relapse will increase [5]. As more surgeons develop a specific interest in breast problems, particularly in relation to screening assessment, so it will become important that audit forms a central role in that process. Failure to demonstrate adequately (more than 4 nodes in the sample) that the axilla is negative, or to undertreat an involved axilla, should in the first place be subject to peer pressure, because soon such mistreatment might be medicolegally indefensible.

It is essential that surgeons in training who have an interest in cancer should be taught the technique of axillary clearance. With experience, this can be carried out with minimal (< 2%) morbidity from shoulder stiffness and arm lymphoedema. The

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