30. Warner W, Whitmore WF Jr. Expected Management of Localized Prostatic Cancer. Abstract and oral communication, Vancouver, Canadian Urological Association, 1990.
31. Schröder FH, Denis L. A European randomized study for screening of adenocarcinoma of the prostate (study protocol), 1991.
32. Ackermann R, Müller HA. Der Wert der perinealen Stanzbiopsie zur Beurtelung des histologischen Differenzierungsgrades des Prostata-Carcinoms. *Verhandl Deutsch Ges Urol* 1981, **32**, 79–81.
33. Livingston RB, Members of the Consensus Development Panel. Consensus Conference. The management of clinically localized prostate cancer. *JAMA* 1987, **258**, 2727–2730.
34. Bagshaw, Kaplan, Jagerman. *Radiology* 1965, **85**, 121–126.
35. Kabalin JN, Hodge KK, McNeal JE, *et al.* Identification of residual cancer in prostate following radiation therapy: role of transrectal ultrasound guided biopsy and prostate following specific antigen. *J Urol* 1989, **142**, 326–331.
36. Werf-Messing BPH van der, Menon RS, Putten WLJ van. Prostatic cancer treated by external irradiation at the Rotterdam Radiotherapy Institute. *Strahlentherapie* 1984, **160**, 293–300.
37. Schellhammer PF, El-Mahdi AM. Local failure and related complications after definitive treatment of carcinoma of the prostate by irradiation or surgery. *Urol Clinics North Am* 1990, **17**, 835–851.
38. Paulson DF, Cline WA Jr, Koefoot RB Jr, *et al.* Extended field radiotherapy versus delayed hormonal therapy in node positive prostatic adenocarcinoma. *J Urol* 1982, **127**, 935.
39. Bagshaw MA, Cox RS, Ray GR. Status of radiation treatment of prostate cancer at Stanford University, *NCI Monograph* 1988, **7**, 47–60.
40. Schröder FH, Belt E. Carcinoma of the prostate: a study of 213 patients with stage C tumors treated by total perineal prostatectomy. *J Urol* 1975, **114**, 257–260.
41. Byar DP, Corle DK, Veterans Administration Cooperative Urological Research Group. VACURG randomized trial of radical prostatectomy for stages I and II prostate cancer. *Urology* 1981, **17**, (Suppl.) 7–11.
42. Graversen PH, Nielsen KT, Gasser TC, Corle DK, Madsen PO. Radical prostatectomy versus expectant primary treatment in stage I and II prostatic cancer. A fifteen-year follow-up. *Urology* 1990, **36**, 493–498.
43. Whitmore WF Jr. Overview: historical and contemporary. *NCI Monograph* 1988, **7**, 7–11.
44. Walsh PC. Radical retropubic prostatectomy with reduced morbidity: an anatomical approach. *NCI Monograph* 1988, **7**, 133–137.

Eur J Cancer, Vol. 29A, No. 5, pp. 661–663, 1993.
Printed in Great Britain

0964–1947/93 $6.00 + 0.00

Cancer Epidemiology and Privacy Laws: Recent Trends in Germany

PARALLEL TO the efforts to establish modern epidemiological research in the Federal Republic of Germany came a rapid increase in public awareness of privacy of various kinds of person-related data. Epidemiological research became a victim of this trend. Mainly affected from this development were (a) projects of analytical epidemiology which needed access to death certificates of the official mortality statistics, (b) descriptive epidemiology despite its use of only aggregated data, and (c) , of course, cancer registration. Publications from that time [1, 2] deplored the restrictions which led to considerable delays of time needed to carry out epidemiological studies.

Those reports may have given rise to the misunderstanding that chiefly the new data protection laws have caused the problems in conducting epidemiological studies in Germany. In fact, however, data were never unprotected. Previous to the privacy laws of the late 1970s, regulations on access to, e.g. death certificates or data of the official mortality statistics existed, but, at the beginning of our first historical cohort studies, *awareness* of those regulations was relatively low. Thus, one effect of the passionate public discussion on data protection was that awareness of existing regulations increased and began to hamper epidemiological research.

On the other hand, hinderance of valuable scientific research has been recognised from the very beginning as an *unwanted* side-effect of the discussion on privacy and the respective legislation. Efforts have been undertaken to specify updates of privacy regulations in order to guarantee prerequisites for scientific research. At present, research regulations of privacy laws can widely be accepted by epidemiologists. However, because problems of epidemiologists do not actually originate from that legislation (or, at least, not only), some of our problems, nevertheless, persist, and will need some further efforts to achieve corresponding improvements in neighbouring fields of legislation.

ANALYTICAL EPIDEMIOLOGY

Well-suited examples for these developments were our experiences during the follow-up of the historical follow-up studies cited above [1, 2]. Parts of the inquiries, especially at the beginning of the follow-up, proceeded without problems, and we were able to get death certificates from the respective health offices through official channels. Later, however, inquiries were increasingly blocked. Importantly, the reasons were quite different and generally not due to the newly passed privacy acts:

(1) Death certificates may by law (*burial laws!*) only be used for the official mortality statistics: these laws do not take scientific research into account; thus, the request for informations has been rejected. The burial laws originated from 1970 and earlier [3].

(2) According to a decree of the respective Federal government, cause of death may, besides the official mortality statistics, only be reported to pension offices. This governmental act originated from 1965.

(3) Professional confidentiality of physicians prohibits communication of causes of death to "third persons". This is regulated in the penal code.

(4) According to decrees of several Federal state governments, cause of death may be communicated, but only if the German

---

Correspondence to N. Becker.

Received 27 Nov. 1992; accepted 4 Dec. 1992.

Cancer Research Center presents the written agreement of the deceased or the nearest relatives.

The privacy laws were only be enacted in the years 1977 and 1978 [4], i.e. much later than the regulations used to deny our claim for death certificates. Interestingly, one federal state interpreted that privacy acts as to concern only living, but not deceased persons. This federal state rejected cooperation on the basis of professional discretion of physicians.

In the majority of cases, health offices were willing to report cause of death, if the consent of the next of kin was given. Thus, we included search for relatives in our follow-up on vital status of study participants. However there were then problems with the residential registries who were our partners in the tracing of vital status, and they believed that they were not allowed to pass on the names and addresses of next of kin. Thus, in this phase of our work we had to discuss each of our steps (tracing vital status by residential registries, search for relatives in residential registries and bureaus of vital statistics, inquiry for cause of death in health offices) with these respective offices, the respective federal ministeries and the data protection authorities; this was done separately in 11 federal states with varying degrees of success. By this, the Federal Republic of Germany has become infamous in hindering medical research by "privacy acts".

The experience that the first versions of privacy acts and corresponding regulations in other laws had as consequence to hamper severly various fields of scientific research has led to remarkable improvements of the privacy act in its revised version of 20 December 1990 [5]. The legitimate demands of research have found entrance by several new paragraphs or specifications within existing paragraphs. As can be seen by the following examples.

Generally, person-related data may only be recorded from the afflicted person directly and with his/her written agreement. However, if this requires a disproportionately high effort, and interests of the afflicted person are not going to be impaired, data may also be recorded without their direct participation. This allows us to build up a cohort for a historical occupational cancer study in the usual way without direct contact with the study participants [1, 2].

Generally, person-related data must be stored anonymously: If, however, this prohibits conduct of a certain research project, person-related data can be stored, and they can be used to link other data relevant for the scope of the research project. The law regulates the mechanism, how to proceed in these cases: person-related data have to be filed separately from other relevant data, such as exposure data or diagnoses; data may only be put together as far as the scope of the research project requires (this means that the scope of the project has to be defined clearly before agreement to obtain the data is given); and person-related data may never leave the institution which has received them for this project.

These new regulations have allowed cancer epidemiologists to establish the following new mechanism to get causes of death in follow-up studies: exposure data and person-related data of vital status are stored separately, as we have done previously. Person-related data (name, address) are needed to carry out the follow-up, so that we have to employ the previously mentioned regulation of exceptions. If follow-up identifies persons who are deceased, we ask the responsible health offices for the death certificates by names and addresses and a code number for each person, and the health offices return causes of death and code numbers without names and addresses to us. In the mean time, the names and addresses have been deleted from our follow-up database, because these person-related data are no longer of interest for our study. Thus, agreement of next of kin is not needed in the future, and time-consuming, tracing for them and asking for consent can be dropped. This simplifies and accelerates our work considerably.

On the other hand, because laws other than the privacy laws have given rise to restrictions, those problems continue to exist and can only be removed step by step by changing the respective laws.

Case-control studies can be carried out in practice if some data protection guidelines are preserved: they must be conducted as a cooperative project with the hospital(s) from which the cases are to be recruited, and physicians have to inform patients on the scope of the interview and obtain their consent to participate (informed consent). This procedure is generally feasible and the participation rate of patients is comparable to international standards [6]. Case recruitment from cancer registries is, however, prohibited by law: cancer registries may not release person-related information on incident cases as normally required for case-control studies. This means, of course, only a restriction for studies to be carried out in regions which are covered by cancer registries. An example is the epidemiological evaluation of fecal occult blood screening in the FRG by a case-control study which would have easily been conducted by access to registry data, but needed the extra effort and time to collect the individual cases by a second survey which have previously been registered [7].

DESCRIPTIVE EPIDEMIOLOGY

Early attempts to limit unwanted consequences of privacy regulations on access to data by research have failed. For example, as early as 1980 the federal law on statistics included a "research clause" (§ 11) which allowed transmission of anonymous and unreidentifiable data to scientists for clearly defined research projects [8]. Mainly projects of descriptive epidemiology were concerned by this law, e.g. cancer atlas projects which are based on the official mortality statistics of the statistical offices of the Federal states. For cancer mapping only cause-specific mortality data aggregated in 5-year-age-groups are required, i.e anonymous, unreidentifiable data. Thus, for common sense, the quoted law allowed free access to such aggregated data.

This was, however, not true. The way of thinking which has been stressed instead may give an impression of the exaggerations which have taken place, but which could now be removed again. In fact, amazing fantasy has been used to hypothesise ways, of how anonymous data might be reidentified; for example, the data for a cancer atlas are aggregated in 5-year-age-groups and are, thus, normally, anonymous. However, in small geographical regions and sometimes in younger age groups a single case of death may occur. Now, it has been argued, if scientists know cause of death, the age group and the region, they could theoretically search on cemetries or in death announcements of newspapers of that region for this unique deceased person of the respective age group and reidentify this person by name and address. In consequence, linkage between name and cause of death would have been possible. Thus, the positive intention of this new "research paragraph" was run aground by an extensive interpretation of the concept of reidentifiability.

For the German cancer atlas [9], we had to meet the arrangement with the statistical offices that these single cases should be eliminated and, additionally, eliminate 2 further cases in another age-group in order to prevent reidentification of the 1 eliminated case by the disagreement of the cause-specific records with the total sum of deaths accessible from routine publications of the statistical offices.

Based on the negative experiences with this "research paragraph", the revised version of the federal law on statistics from the year 1984 [8] included a specified paragraph (§ 16), which does not put emphasis upon technical exclusion in the possibility of reidentification. Anonymous data may be received for clearly defined research projects, even if reindentification cannot be completely excluded; emphasis is put now on the condition that the theoretically possible reidentification would require a disproportionately high expenditure of time, costs and work.

CANCER REGISTRIES

Registries for cancer incidence exist, thus far, only as regional registries in Hamburg and in the Saarland. Cancer registration was, of course, most directly and seriously concerned by data protection legislation. Work of the cancer registry in the Saarland had to be suspended after enaction of the federal data protection law in 27 January 1977. A special law for this register allowed reactivation in the year 1979. This is in accordance with the general demand of the privacy act that person-related data may be processed only if the concerned person has agreed or a specified act allows and regulates it. Because the Saarland register does not ask cancer patients for agreement, a specified act had to be installed. Case-recruitment for epidemiological case-control studies remains, however, prohibited by the new legislation. A similar mechanism was to be initiated to save already collected data and future work of the country-wide register of the former GDR after German unification. This register had also to stop its work immediately after unification, but the atmosphere is nowadays more clearly pro cancer registration.

At the moment, in all Federal states of Germany, cancer registration acts are in preparation. Reporting mechanisms are, however, still under discussion. The present legal framework allows the installation of all variants of reporting procedures, including those which are the most recommended for a powerful epidemiological use of the registry data. It is purely a political decision which regulation will finally be enacted.

CONCLUSIONS

Privacy acts of the late 1970s and similar regulations of older laws tended to severly hamper epidemiological research in Germany. Developments of the recent years allow, however, a more optimistic interpretation. These privacy acts can be considered as first attempts of working in a new field of legislation, having had some very unpleasant effects on scientific research. Updates made in recent years show that efforts have been undertaken to create juristic rules that enable scientific research within the framework of privacy standards. Most of these new regulations we can live with, but some of the old laws, still in operation, continue to hamper work of cancer epidemiology and need further endeavours to modify them.

European cooperation is attempting to harmonise national privacy regulations. Epidemiologists should follow closely these discussions and put forward their research requirements. The German example shows that one-sided emphasis upon privacy may injure biomedical research considerably. It also shows, however, that juristic standards can be developed which make research requirements consistent with privacy legislation. This goal is what we should aspire to.

Nikolaus Becker
German Cancer Research Center
Division of Epidemiology
Im Neuenheimer Feld 280
D-6900 Heidelberg, F.R.G.

---

1. Claude J, Frentzel-Beyme R. A mortality study of workers employed in a German rock wool factory. *Scan J Work Environ Health* 1984, **10**, 151–157.
2. Becker N, Claude J, Frentzel-Beyme R. Cancer risk of arc welders exposed to fumes containing chromium and nickel. *Scan J Work Environ Health* 1985, **11**, 75–82.
3. Dürig G. Verwaltungsgesetze des Landes Baden-Württemberg. Bestattungsgesetz vom 21 Juli 1970. Beck, München.
4. Gola P, Hümmerich K, Kerstan U. Datenschutzrecht I, II, III. Schweitzer, Berlin, I 1977, II 1978, III 1979.
5. Dörr E, Schmidt D. Neues Bundesdatenschutzgesetz. Handkommentar. Datakontext-Verlag. Köln 1991.
6. Schlehofer B, Blettner M, Becker N, Martinsohn C, Wahrendorf J. Medical risk factors and the development of brain tumors. *Cancer* 1992, **69**, 2541–2547.
7. Robra B-P, Wahrendorf J. Fecal Occult Blood Screening in the Federal Republic of Germany. In Hardcastle JD, ed. *Screening for Colorectal Cancer*. Normed, Bad Homburg 1990, 70–77.
8. Dorer P, Mainusch H, Tubies H. Bundesstatistikgesetz. Kommentar. Beck. München 1988.
9. Becker N, Frentzel-Beyme R, Wagner G. *Atlas of Cancer Mortality in the Federal Republic of Germany* Second Edition, Berlin, Springer 1984.

Eur J Cancer, Vol. 29A, No. 5, p. 663, 1993.
Printed in Great Britain

0964–1947/93 $6.00 + 0.00
Pergamon Press Ltd

Education and Training in Oncology

THIS ISSUE of the European Journal of Cancer contains the first in what will be a biannual feature. 'Education and Training in Oncology', edited by Dr Alberto Costa, Director of the European School of Oncology in Milan, will contain articles of international interest on all aspects of education and training as well as a directory of European-based courses.

We would be pleased to consider information on courses in oncology for publication in the next issue of 'ETO', and application forms are available from the European School of Oncology at the address on page 791.

Michael Peckham
Editor in Chief
European Journal of Cancer