

The use of personal data from medical records and biological materials: ethical perspectives and the basis for legal restrictions in health research

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Abstract

This paper discusses the moral justification for using personal data without informed consent, from both medical records and biological materials, in research where subjects are not physically present in the study and will never have any contact with the study investigators. Although the idea of waiving the requirement for informed consent in certain investigations has been mentioned in several ethical guidelines formulated by epidemiologists and physicians since the late 1980s, these guidelines are now of limited use due to legal restrictions on the use of personal data in most western countries. Several misconceptions that form the basis for legal restriction of health research are discussed: lack of knowledge of the need to link personal information from health services with personal information produced outside the health system in many biomedical investigations; the assumption of a deterministic model of disease causation in which the prediction of disease occurrence is based on a genetic association despite the fact that most genotypes for common diseases are incompletely penetrant; the lack of a logical rationale for the recommendation in the Declaration of Helsinki that only research that offers some benefit to study subjects is justified; the great lack of knowledge about research methodology revealed in some alternatives proposed to avoid using personal data; and the lack of a debate about the ethical double standard of institutions and investigators in countries that prohibit the use of personal data but finance and carry out studies in other countries where it is permitted.

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Keywords: Biological materials; Medical records; Personal data; Health; Ethics

Introduction

Most health professionals, citizens and political representatives know that advances in the knowledge of the aetiology, clinical characteristics, prognosis and treatment of diseases would be seriously impaired if investigators were unable to consult personal information contained in medical records or the archives of biological samples. Much less widely known, however, is the fact that many of these investigations have been carried out by linking different medical and non-medical records and archives. And what is undoubtedly known to only a few is that many of these investigations would not have been possible had it been necessary to obtain

the consent of the study subjects to use their personal data contained in medical registries or in the archives of biological materials.

In recent years, however, enormous technological advances have made it possible to collect and store personal data and specimens of body fluids and tissues for long periods of time. This has sparked a widespread debate on issues of privacy and confidentiality in relation to the use of personal information from both computerised medical records and stored biological materials, especially genetic material. Closely associated with this debate is the current dispute about whether it is ethically correct to use for research purposes personal data and biological specimens that were collected for diagnostic, therapeutic or other reasons. To what extent should ethical and legal norms on informed consent in

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research be strengthened without imposing limitations on biomedical and epidemiological research using personal data? Can we identify situations in which the use of personal data without informed consent involves no risk for study subjects?

All biomedical and epidemiological research that requires the physical presence of persons should be carried out in accordance with the World Medical Association's ethical principles of research on human subjects, as stated in the Declaration of Helsinki and its subsequent revisions (*Declaration of Helsinki, 1964*), which consider informed consent to be a *sine qua non* condition. That is, research subjects must give their voluntary consent after being informed of the objectives, methods and possible benefits and risk of the investigation, as well as of any possible disadvantages involved in the research, and of their right to withdraw from the study at any time. The need for informed consent in research with human subjects is also included in the conclusions of a report of *The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research of the US Congress (1979)*, whose ethical principles have been widely adopted in the Western world. However, the role of informed consent is less evident in many investigations that use personal information from surveys, reporting systems, registries or other types of repositories of data or biological samples, since the use of these data or materials does not involve any physical risk to the research subjects, and any other potential harm is less clear. Furthermore, it may be very difficult to obtain informed consent in many cases.

Here I consider only research using personal information in which the research subjects are not physically present in the study and will never have any contact with the study investigators. I refer to personal data and biological specimens collected for any reason. I exclude those investigations in which additional personal information or new biological material is collected to link it with stored personal data, since in these cases the subject is physically present. From an ethical point of view, personal data from any type of record and personal data from biological materials are considered to the same. A recent recommendation of the US National Bioethics Advisory Commission on ethical aspects in research with human biological materials also highlighted the need to standardise legal norms regulating research based on medical records and human biological materials (*NBAC, 1999*).

Two ethical dilemmas in the use of personal data for research

In many biomedical and epidemiological investigations that do not require the physical presence of

research subjects, it is not feasible to obtain informed consent, either because the research includes a large number of persons or because information is needed from deceased persons and it would not be possible to locate relatives. Some investigations even require the linkage of personal records generated decades ago for other purposes, records that no one could then have imagined to have any other use, since the study could not have been conceived given the state of knowledge at the time the information was collected (*Lako, 1986; Doll, 2001*). Likewise, over the last 50 years the use of archives of human specimens collected in the course of health care has frequently given rise to great advances in medical knowledge, which have produced important benefits for mankind (*Korn, 2000*).

These situations raise the question of whether it is ethically appropriate for information and biological samples collected and stored to be used for research without personal consent. Thus, an ethical conflict arises between the value of knowledge in itself and as a means to improve the quality of human life, and the rights to autonomy and personal privacy. Privacy can be considered a right, that is, the right of a person to control other people's access to personal data (*Couglin & Beauchamp, 1992*). The use of biological material or of information collected in medical records without the consent of study subjects constitutes a wrong because the right to privacy has been violated. But this violation is a harm more theoretical than real, since it is unreasonable to say that an individual's autonomy has been violated if confidentiality is maintained (*Capron, 1991*). Confidentiality is violated only if a person to whom the information was revealed in confidence does not comply with the obligation to protect the information. As a general rule, once personal data have been collected or biological material has been extracted from the body, there is greater interest in maintaining the confidentiality of the data and the information derived from the material than in maintaining the individual's privacy.

But the obligation to protect confidential information does not mean that this information cannot be used. The clearest example is the transmission of confidential clinical information on patients between physicians in order to make decisions about diagnosis, treatment or prognosis, without the patient having to give express authorisation each time physicians share information for decision making.

Another ethical conflict is produced due to the existence of an ethical double standard in this area. Whereas some countries and communities allow personal data and biological samples to be used for research without informed consent if the study does not require the physical presence of research subjects, in other places this type of investigation is not permitted. It is likely that many people believe there is no ethical justification for

limiting individual autonomy in some situations while protecting it in similar situations in other places by requiring the subject's consent for the use of personal data.

Moral justification for using personal data without informed consent in research

The use of personal information without the individual's consent violates Kant's categorical imperative that human beings are ends and not means. This categorical imperative—widely accepted in biomedical ethics—acts as a canon, as a system of moral reference, to determine if human actions are good or bad. When research subjects give their consent to participate in research, this consent justifies their participation as a means (Beauchamp, 1996), since the individual knows and assumes the risks involved in the research. However, the use of data and human biological samples without consent, but in the absence of any physical or mental harm, could also become a universal maxim when the research involves a benefit to society and possibly to the persons themselves. Thus, the fact that informed consent is omitted in these cases cannot be considered as something intrinsically bad, although neither can it be considered as something completely good.

The canon of morality has a merely formal nature and cannot be used to make specific moral judgments. It affirms that we must respect human beings, but it does not say what actions we must take to do so. For this reason, more specific ethical principles have been formulated. As mentioned, the most widely accepted principles in biomedical ethics in the Western world are those proposed by the Belmont Report (*The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, 1979) and, subsequently, by Beauchamp and Childress (1994): respect for autonomy, non-maleficence, beneficence and justice.

When analysing ethical rightness, however, we often find conflicts among principles. These principles cannot be used to resolve conflicts in such cases since, like all general moral norms, they are abstract instruments offering vague advice, and are of little use in resolving profound and complex moral problems. It seems clear that the principle of autonomy should rank higher than that of beneficence, since a person cannot be unwillingly forced to participate in research that is assumed to produce a benefit, but there may be exceptional circumstances in which this is not so. This would be the case of investigations in unconscious persons or in emergency situations when it is not possible to request informed consent (Biros et al., 1985). Likewise, society weighs the principle of justice more highly than that of autonomy when the State, in the name of the common

good, obliges persons to be vaccinated against a highly infectious disease to protect the public health.

When the analysis of what is ethically right reveals conflicts between principles, one way to proceed in our moral reasoning in order to reduce conflicts is to specify and interpret the principles in each specific problem and to evaluate the consequences to determine which of the conflicting principles should be ranked higher. In weighing the consequences, one judges the benefit–risk relation and the distribution of benefits and risks. The objective of all research is to produce knowledge that can be generalised, and in the specific case at hand, we assume that this knowledge can be used to improve the health and well-being of human beings. For this reason, it is difficult to judge whether the risks are reasonable in relation to the potential increase in knowledge, since those who participate in research are frequently not the same as those who benefit from it (NABC, 2001). When the risk is minimal or less than minimal, understood as the level of risk that everyone assumes in the normal activities of daily living, a minimal benefit or even no benefit would be compatible with respect for the non-maleficence principle. This is the case in investigations in which research subjects are not physically present and will never have any contact with study investigators, since all that is needed is access to their personal data; thus, there is no physical or psychological harm due to the invasion of privacy without consent.

For reasons of feasibility, the burden of these investigations always falls on persons with stored personal data or biological materials who live in communities where this type of research is permitted. However, this situation does not violate the criterion of distributive justice, since nothing excludes the research subjects from the possible benefits that may be derived from it. Furthermore, given that the benefits and risks of research are not always evaluated in the same way in all places, the formal principle of justice “to treat like cases alike” is not violated either, since there are differences that make it difficult to apply the rule “if it is not ethical to carry out an investigation in one place, then it is not ethical to carry out that study in any other place.”

It can be concluded, therefore, that in weighing the consequences, the benefits to society weigh more than the harm attributable to the invasion of privacy, so long as the use of personal data without informed consent is the only way to answer a research question, and confidentiality and personal integrity remain intact.

The gradual subordination of moral reasoning to the rule of law

A number of authors (Gostin & Hadley, 1988; Wald et al., 1994; Beauchamp, 1996; Coughlin, Soskolne, & Goodman, 1997) and several ethical guidelines formu-

lated by epidemiologists since the late 1980s have reached the former conclusion (Last, 1990; Beauchamp et al., 1991; Council for International Organization of Medical Sciences, 1991). These ethical guidelines stipulate that decisions about the use of personal information should be made, not by the investigator, but by an institutional review board. Furthermore, some authors believe that this type of research does not require the approval of an independent ethical committee. For example, a report of a Working Group for the Royal College of Physicians Committee on Ethical Issues in Medicine (1994) proposed that research requiring access to medical records or to stored biologic samples, without direct patient participation, does not require the explicit consent of patients or review by an independent institutional review board, as long as explicit consent is obtained from the person officially responsible for the records or from the physician caring for the patient, and as long as the confidentiality of the information is guaranteed by the professional ethical code.

However, the guidelines in this regard are of limited use, now that laws are being passed in most Western countries to regulate how and for what purpose the use of personal data is permitted from different records and stored biological samples. Moral norms should undoubtedly be converted into a minimum set of commonly agreed laws that make it possible to live together in a democratic society. But the problem lies in the fact that what should be the result of a process of moral reasoning within the institutional review boards to identify and resolve the ethical problems raised by each type of investigation is becoming an exclusively legal affair.

Several articles published in different medical research journals in the late 1990s noted how legislation in various parts of the world was restricting biomedical and epidemiological research in the use of personal data from medical records. In the United States, for example, where several states have incorporated this type of legislation in their legal systems (Wukadinovich & Coughlin 1999), one author warned of the important social consequences that could result from excessively restricting access to medical data for research (Melton, 1997). Such measures could make it difficult or practically impossible to monitor the health of the population and to detect emerging diseases, to identify risk factors of disease, to evaluate the effectiveness of treatment or to quantify prognoses (Melton, 1997).

In the European Union, the directive approved by the European Parliament restricts access to these types of data unless previous consent has been obtained from the subject, but permits member states to make exceptions in the case of health-related research in the public interest (Directive 95/46/EC, 1995). In some countries, however, it appears that this exception will not be incorporated into the legal system. This is the case of

Holland, where strict regulation in these matters makes it impossible to link registries, even if they are anonymised (Vanderbroucke, 1998). In addition, legislation encourages physicians to destroy records after 10–15 years, making it impossible to carry out many investigations like those that have helped advance biomedical and epidemiological knowledge in the last 50 years.

In other countries, uncertainty about the interpretation of the law greatly limits research. This is the case in the United Kingdom, where the new 1998 Data Protection Act constitutes the implementation of the European Union directive (Strobl, Cave, & Walley, 2000). The different interpretations of this law and the obligation for confidentiality limit multicentre epidemiological studies because some hospitals require the patient's explicit consent before permitting investigators to use their records, a process that considerably delays the research or makes it impossible to carry out due to the cost or difficulty of contacting patients or their relatives in case of death.

Surprisingly, in some countries like Spain, where there is legislation addressing the possibility of accessing personal data for biomedical and epidemiological research, the probability of actually being able to carry out these investigations is very low. This occurs either because most institutions responsible for safeguarding the data interpret the legislation in the most restrictive way possible and do not grant the investigators' requests or because the legal system restricts the use of data from some types of records. For example, since 1994 it has been forbidden to use information on the cause of death shown in the Registry Office until 25 years after the date of death (Ministerio de Justicia e Interior, 1994). The situation is quite similar in other European Union countries, which creates considerable uncertainty among investigators about whether or not it is possible to use personal data.

It is truly surprising that, at a time when mankind is experiencing the greatest developments in information technology, we are limiting the use of personal information that can be used for the common good. What is more, researchers sometimes decide not to collect personal information because it is assumed that there is a high probability that the information will be used in a discriminating way (Woodward, 1995; Woodward, 1999; Welch, 2001) or simply to avoid facing the ethical dilemma of using it without informed consent.

Basis for legal restriction

Different reductionist conceptions of health research, together with a series of subjective or irrational arguments with little empirical basis about the methodology and risks involved in the use of personal

data in research have played a major role in this phenomenon.

Reductionist considerations about health research

The controlled clinical trial is generally agreed to be the paradigm for health research, thus most ethical debates on research in human subjects revolve around this type of design. However, there has been little ethical debate about non-experimental studies, which means that legislative decisions concerning these types of studies are unlikely to be completely informed. For example, the proliferation of opinion articles focusing on whether investigators from developed countries should or should not use their own countries' ethical standards as a frame of reference for research in the underdeveloped world—the most recent of them concerning the placebo-controlled trials of new regimens to prevent the vertical transmission of HIV in developing countries—(Lurie & Wolf, 1997; Angell, 1997; Varmus & Satcher, 1997), stands in contrast to the absence of a similar debate about the ethical double standard that currently exists in the developed countries with regard to research using personal data from registries and stored biological samples. Whereas in some places these data may be used without informed consent for research that does not require the physical presence of the research subjects, in other places this type of investigation is not permitted. However, this does not stop many institutions and investigators in countries that prohibit this type of investigation from financing and carrying out studies in other countries where it is permitted.

The complaints of some authors about limits on the use of personal data from medical records or stored biological samples do not help to solve the problem, because they do not take into account that many clinical investigations evaluating disease prognosis or the side effects of some treatments require information from non-medical records available in offices of statistics, departments of ministries or other public institutions, or in private companies, which also do not permit personal data to be used for ends other than those for which it was collected (Beauchamp et al., 1991).

The use of personal health information is a fundamental requirement for quality research in the health services (Gostin & Hadley, 1988; Chamberlayne et al., 1998), but such information could potentially generate much more knowledge if it could be linked with personal information produced outside the health system. For example, the estimation of survival time after treatment requires investigators to know whether patients are alive or dead after a certain follow-up period; frequently, this can only be done by determining if they are included in the mortality registry, which in many countries is located in institutions outside the health system. In other cases, the only way to evaluate the prognosis of a particular

disease may be by using social security registries, which show the date on which an individual began to receive a subsidy for a disability or handicap produced as a result of the disease. Sometimes various registries are linked, as in the case of research carried out in the United States to determine some side effects of clozapine on mortality; in this study, information on almost 70,000 patients from the Clozaril National Registry was linked with information on these patients contained in the Social Security Death Files and in the files of the National Death Index (Walker, Lanza, Arellano, & Rothman, 1997). Likewise, in the first epidemiological study that examined the association between cellular phone use and traffic accidents, carried out in Toronto, investigators had to determine if drivers who had had an accident were using the telephone seconds before the accident occurred. They did this by linking the name of the injured drivers shown in the traffic authority's registry of injuries—which includes the time when the accident occurred—with the telephone company registry—which shows the time when each client's phone call was made (Redelmeier & Tibshirani, 1997).

The reductionist view of health research is clearly apparent in an alternative that has been proposed for the use of personal data in any research: patients would be requested to authorise use of their personal data at the time of contact with the health centre or physician, or when the biological samples are taken (Wright et al., 1995; Wukadinovich & Coughlin, 1999). This is what has been termed prospective consent or blanket consent. However, this proposal is ethically unjustified because such authorisation lacks other essential elements of informed consent and does not constitute real informed consent. Nor does this proposal answer the problem posed by research using personal data gathered several decades ago for other purposes, which no one could have then imagined would have any further use. In addition, it focuses only on personal data contained in medical registries and repositories for biological samples, without considering research which requires linking these data with personal information from non-health institutions. Such a proposal also ignores the fact that the subjects of many investigations are persons who do not necessarily use the health services.

This conception of health research can be seen in certain regulations that include exceptions making it possible to use personal data without consent. Thus, the Health Insurance Portability and Accountability Act authorises the US Department of Health and Human Services to regulate only those institutions that routinely collect sensitive medical information (Gostin, 2001). Therefore, even though the National Privacy Rule envisages the possibility of using personal data for research in some cases without the patient's consent, after the study protocol has been subjected to rigorous ethical and scientific evaluation, it will still not be

possible to reply to countless health-related research questions.

Another reductionist assumption is the belief that the causes of diseases are exclusively biological, despite substantial empirical evidence of the importance of social and economic factors in disease aetiology (Berkman & Kawachi, 2000). Some authors go further in this biological conception by implicitly assuming a determinist model of disease causation: they oppose the use of personal data related with genetic material because they believe any genetic information to be a predisposing cause of disease (Annas, 1993; Doyal, 1997; Annas, 2001).

This view contrasts with the uncertainty that currently exists about whether it will some day be possible to predict genetically the majority of the most common diseases, given their genetic complexity (Abbott, 2000). Some authors have pointed out that the sequencing of the human genome will make it possible to identify the genes that cause Mendelian disorders (Holtzman & Marteu, 2000), and to develop the corresponding diagnostic and predictive tests; however, only a small proportion of the population suffers from these types of disorders. On the contrary, most genotypes for common diseases are incompletely penetrant, therefore associations between the genotype and the phenotype are weak and it is unlikely such diseases can be predicted. In fact, the genes that have been shown to be associated with the development of some chronic diseases or cancer are responsible for a very small percentage of cases (Holtzman & Marteu, 2000). As one author has pointed out, advances in the knowledge of disease causation will require the development of theories that integrate genetic factors—or other biological factors—in a broad context of cultural, social and lifestyle factors (Diez-Roux, 1998). Personal data, including genetic information, will be needed to test these theories empirically.

Irrational arguments about health research

According to the ethical principals derived from successive versions of the Declaration of Helsinki on medical research in human subjects, only research that offers some benefit to study subjects is justified. That is, the Declaration considers that in any medical research, the subject's well-being should prevail over the interests of science and of society. This is why some authors favour informed consent when personal information from medical records or biological samples is used (Woodward, 1995, 1999; Welch, 2001). Although this theory leaves no room for moral reasoning, it is what has, in large measure, informed the opinion of legislators. However, the Belmont Report noted that good clinical practice should be based on scientific knowledge, therefore clinical research is justified to the extent that it makes it possible to evaluate good clinical practice.

Subsequent to this validation process, the research should be conducted in accordance with the ethical principles and norms of respect for human beings. Likewise, in the most recent report of the National Bioethics Advisory Commission (NBAC, 2001) on ethical principals in research with human beings, it is considered that the objective of research is to produce knowledge that will benefit society and that, even though participation may benefit a particular individual, this is not the real objective.

Lack of knowledge of non-experimental research methodology may lead to highly irrational statements. For example, one author (Riis, 2000) refers to the lost opportunity in the 2000 Declaration of Helsinki, which briefly mentions the use of human materials and personal data (World Medical Association, 2000), but does not comment on the studies that use these kinds of data. However, after reading this author's reflections and arguments, the reader wonders whether he really understands what it means to use personal data in biomedical and epidemiological research, given that he considers it a limitation of the Declaration the fact that it does not explicitly mention that the information should be anonymous. Surprisingly, these contradictory kinds of arguments are also frequently found among some experts in bioethics who support the use of personal data without the consent of research subjects in certain situations. Some authors propose the creation of a numeric code to identify each individual, although it is not clear whether this code should always be the same for each subject in all registries; neither is it explained exactly how investigators would access these data nor what persons or institutions should be responsible for safeguarding data confidentiality (Horner, 1998; Strobl, Cave, & Walley, 2000). Other authors maintain that identifying information should be eliminated from registries to which investigators have access (Doyal, 1997) or, alternatively, that data from registries should be aggregated just before the analysis is made (Horner, 1998).

One can only imagine from such proposals that a supernatural being will carry out the research, since they reveal a great lack of knowledge of the methods used in these types of research. A unique numeric code is a necessary, but not sufficient, condition for tracking research subjects; therefore, it is necessary to use other personal characteristics such as name, date of birth, sex, place of birth, etc., to avoid losing a large number of cases with the consequent bias in the estimates. In addition, eliminating personal identifiers from registries makes it impossible to avoid duplicate cases, with the consequent effect on the validity of the results. Likewise, investigators would not be able to link information on each research patient with information contained in different medical records. Finally, the proposal to aggregate the data before the investigator can use it

does not make clear how or who will link the registries and aggregate the data. The investigator needs to continually make decisions about the data analysis or about whether or not to include certain variables, thus the research process will be limited to a greater or lesser extent depending on how the linkage or aggregation is carried out and who is responsible for it.

It has also been recommended that research should be carried out with anonymous data when informed consent cannot be obtained (Woodward, 1999), overlooking the fact that the research questions, the study design and the scientific relevance of the results are all totally different depending on whether or not personal data are used. Another author has stated that medical registries containing personal identification are not needed to guarantee the quality of health care, to detect fraud or for other public health activities (Welch, 2001). In this author's opinion, mathematical algorithms applied to anonymous data often perform these functions faster, more efficiently, more precisely and at a lower cost. Without a more specific explanation of these algorithms, however, it is impossible to imagine how these results can be obtained with anonymous data.

Subjective arguments about health research

It has been said that when evaluating whether informed consent might be waived in certain cases, one criterion to be considered in weighing the risks and benefits should be the feasibility of obtaining consent, since it may be that obtaining consent is not feasible but that there is no other way to carry out the research (Doyal, 1997). Some investigations have very large numbers of participants—up to millions in many epidemiological studies—and it is obviously impossible to ask for informed consent in these cases, but investigations usually vary widely in the size of the study population. Because this criterion of feasibility is subjective, the editor of one biomedical research journal wondered where one draws the line with regard to the number of study participants when deciding whether or not to publish a study in which informed consent was not requested (Smith, 1997).

It has also been suggested that a possible risk that may result from breaching confidentiality when using personal information is discrimination against persons. Persons who have particular health problems or certain characteristics that increase the risk of disease may suffer some type of discrimination in obtaining and/or keeping a job or some type of health or life insurance (Council on Ethical and Judicial Affairs and American Medical Association, 1991; Harper, 1993; Hudson et al., 1995; Coughlin, 1996; NBAC, 1999). To some authors the risk is greater with the genetic information (Annas, 1993). However, until now most of these arguments have little basis in fact. For example, the information

available about discrimination on a genetic basis comes from surveys in which individuals respond about their perception of discrimination, but there is no independent verification of their perception (Davison, Macintyre, & Smith 1994; Lapham, Kozma, & Weiss, 1996; Watts, 1999; NBAC, 1999).

Surprisingly, these fears stand in contrast to a great many situations which also may involve a risk of revealing and inappropriately using personal data containing sensitive information, but we do not for this reason relinquish the possibility of collecting and using this information. Furthermore, society sometimes accepts the use of personal data without informed consent, because it is assumed that a benefit for the common good will be obtained. Thus, the distribution of income in developed countries with the so-called Welfare State system requires a suitable system of taxes that will minimise fraud. The government has access to different sources containing personal information about each citizen's income so that administrative and legal action can be taken against those who do not contribute to the common good. Likewise, an up-to-date electoral census with a minimum set of personal data is a basic requirement for a democratic society. In most countries, political parties taking part in elections have access to these personal data in order to distribute their electoral programme to each citizen. In a similar way, in the case of an epidemic of some communicable disease, health authorities use personal data without the informed consent of subjects to identify characteristics of the epidemic that will make it possible to develop intervention measures to impede its spread. Discrimination due to the inappropriate use of any kind of personal information does not depend on the existence of stored personal data, but on the lack of the necessary mechanisms to protect confidentiality, and on the absence of sanctions when this type of information is accessed or revealed for ends other than those which society believes are appropriate.

There is no question that certain moral values in any society may have equal or greater weight than the freedom of scientific investigation, although there is controversy about how to assign this weight, and it is not easy to reach a consensus (Coughlin, 1996). However, Rothman's predictions over 20 years ago about the future of epidemiological research can be considered optimistic if this consensus is achieved based on reductionist, irrational or subjective arguments. In a well-known article (Rothman, 1981) this author imagined what the field of epidemiology might look like from the perspective of someone living in the year 2004. He noted that institutional review boards had played an important role in evaluating matters related with privacy, ethics and the protection of human rights in research projects in the final years of the 20th century, but that bureaucratic implementation had made it

increasingly costly to carry out epidemiological studies because of variations in how informed consent was interpreted by each institution's review boards. Thus, he surmised, it was not surprising that few scientifically relevant studies were published, most of which were ecological studies based on routine population statistics such as Farr's studies in the early 19th century. Rothman's prediction was probably premature, and he may well not have gone far enough: with restrictions on the use of personal data from medical records and stored biological, even studies like Farr's probably could not be carried out.

Conclusions: prerequisites for the search for solutions

To date, the debate about the use of personal data without informed consent has focused mainly on biomedical and epidemiological research; however, this limitation affects other scientific disciplines, as well. For example, in most countries researchers cannot study the influence of circumstances related with people's occupations on the level of income at the end of their economically active lives, since it is not permitted to link personal data from Social Security files with information on individuals contained in the tax registry of the Public Treasury, despite the fact that the results of this type of research would provide rational foundations for public policy on pensions. This restriction also limits the linkage of population statistics with the birth registry or with the registry of abortions, making it impossible to estimate the effect of women's social and economic circumstances on the number of children or the number of induced abortions, despite the importance of such results for policies affecting the family. One could cite a variety of examples, but these two are sufficient to illustrate that a genuine social debate about the use of personal data without the informed consent of study subjects will be legitimate only when there is participation by all the scientific disciplines involved. This would eliminate most of the reductionist arguments. This will not be an easy task because the lack of mutual fertilisation makes it difficult to share the specific results provided by each scientific discipline, and to identify common methodological strategies used by each discipline to test hypotheses.

In any case, researchers are not the only ones who should participate in the debate. The conflict of interest related with their professional activity is probably an obstacle to ethical self-regulation. For this reason, representatives of different social groups and of specific communities—some of whom may legitimately want to apply moral principals differently—together with experts in bioethics and investigators should reach agreements, avoiding, or at least reducing to a minimum, the irrational and subjective lines of reasoning

that are argued in this debate. For example, it should be clearly accepted that the use of personal data is only a methodological requirement for carrying out research; its objective is to generate knowledge by means of reasonably valid estimates, but not necessarily to benefit the specific individuals who are the subjects of the study. Thus, it is completely illogical that one criterion used in some cases (Wright et al., 1995; NBAC, 2001) for the use of personal data without informed consent is the possibility of locating the study subjects if the results of the investigation so require. In the same way, it would be totally irrational if a breach of confidentiality during the research process had some administrative or legal repercussion on a specific individual.

Finally, the ethical double standard that exists in research with personal data without informed consent should not be allowed to continue much longer. The same as in other recent areas of research with human subjects which involve an ethical dilemma, an appropriate solution will not be found so long as the regulation of research is left in the hands of each individual country or region (Evers, 2002). Although this ethical double standard does not violate the criteria of distributive and formal justice, an observer might wonder why countries or communities that reject certain types of investigations will at the same time accept the benefits that may be derived from research done outside their borders, research to which they often contribute funds or investigators. Perhaps the answer to this question requires another concept of justice. For example, a principle of justice stipulating that no one has the right to benefit from historical, cultural or social differences unless the study subjects or the communities where the studies are carried out can accept that other individuals or communities will never be study subjects due to these differences, but will benefit from the study results. Consideration of this criterion of justice, or of any other that responds to the ethical dilemma about the use of personal data, will only take place when the entire international community participates in the debate and manages to find common positions, not only in this matter but also in other complex ethical dilemmas in research.

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