

# Use of personal data in epidemiological research in Europe

*Report of a survey conducted by the IEA European Epidemiology Federation*

The aim of the recent EU directive on data protection<sup>1</sup> was to facilitate the transmission of information within Europe. Such a directive has profound implications for research, especially epidemiological research, but that was not recognized until late in the process of approval of the directive.

However the final text did take research into consideration and allowed exemptions under specified circumstances for the use of, for example, medical data for research even without informed consent.

Until now, no one had studied how the directive was used in Europe nor its implications for the use of registries in epidemiological research. We circulated a questionnaire to the European members of IEA and national societies of epidemiology. We urged epidemiologists to respond who had sought permission to get data during the last 5 years from the Data Inspectorate or had done research using national registries.

The survey aimed to collect information both on how the EU directive had changed the national regulations and on the current situation in the EU member states. It was intended that the results of the survey might be used in discussions with the EU committee and the Council of Europe. It was also hoped that this international comparison might describe the strategies epidemiologists use for dealing with EU regulations.

The survey results have now been summarized in a report in the December 2004 issue of the International Journal of Epidemiology.<sup>2</sup> The questionnaire is given below.

1. [http://www.europa.eu.int/eur-lex/en/lif/dat/1995/en\\_395L0046.html](http://www.europa.eu.int/eur-lex/en/lif/dat/1995/en_395L0046.html)
2. De Vet HCW, Dekker JM, van Veen EB, Olsen J. Access to data from European registries for epidemiological research: results from a survey by the International Epidemiological Association European Federation. Int J Epidemiol 2003;32:1114-5.

## **The IEA data directive group**

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Mark the answering option that applies most to the situation in your country

<b>1.</b>	<b>Which country do you come from?</b>		
First a few questions about the existing regulation with respect to use of registers for epidemiologic research			
<b>2.</b>	<b>When was the EU-Directive implemented in your country?</b>		
	Year of implementation		
	Not implemented		Go to Question 4
	I do not know		
<b>3.</b>	<b>In general, has the directive made epidemiological research</b>		
	More difficult		
	No change		
	Less difficult		
	I do not know		
<b>4.</b>	<b>Does your country have national legislation on data protection with bearing on epidemiological research?</b>		
	No		Go to Question 6
	Yes		
	I do not know		
<b>5.</b>	<b>Is this legislation based on the EU directive?</b>		
	Yes		
	No		

The next questions address a number of research options. We ask you to state how the legal authorities in your country deal with the issue of data protection			
<b>6a.</b>	<b>You want to use information from medical records on health outcomes and intervention characteristics for patients who are still alive. Will it be possible to get the information without informed consent (given you don't need to contact the patients).</b>		
	It is not possible		
	It is possible, but very difficult		
	It is possible		
	I do not know		
<b>6b.</b>	<b>Would the situation be different if the patients were no longer alive (had died within the last 20 years)?</b>		
	The situation would be the same		
	It would be more difficult to get data		
	It would be easier to get data		
	I do not know		
<b>7a.</b>	<b>Many countries keep public registers on MORTALITY. Do you have such registers in your country?</b>		
	No		Go to question 8
	Yes, and data are identifiable at the individual level		
	Yes, but data are not identifiable at the individual level		
	Please give information on special conditions, if adequate, and how it works.		

<b>7b.</b>	<b>Could data from these registers be used in an entirely register-based research project?</b>		
	No, they cannot be used		
	Yes, but only after individual consent		
	Yes, they can be used without individual consent		
<b>7c.</b>			
	<b>Could data from these registers be linked to research data, which were collected by you or others?</b>		
	Not possible (personal identifiers are not available)		
	Yes, linkage is possible but only after individual consent.		
	Yes, linkage is possible without consent		
<b>8a.</b>			
	<b>Many countries keep registers on GENERAL DISEASE, CANCER OR OTHER DISEASES. Which registers exist in your country?</b>		
	Name:		
If your country does not have a register for general diseases but only for specific diseases, indicate for which register the following answers apply.			
<b>8b.</b>	<b>Are data identifiable at the individual level</b>		
	No		
	Yes		
	Please give informaton on special conditons, if adequate, and how it works		
<b>9a.</b>			
	<b>Could data from these registers be used in an entirely register-based research project?</b>		
	No, they cannot be used		
	Yes, but only after individual consent		
	Yes, they can be used without individual consent		

<b>9b.</b>	<b>Could data from these registers be linked to research data, which were collected by you or others?</b>		
	Not possible (personal identifiers are not available)		
	Yes, linkage is possible but only after individual consent		
	Yes, linkage is possible without consent		
<b>10a.</b>	<b>Can stored research data with personal identifiers be used for another research purpose that requires NO PERSONAL CONTACT to study members?</b>		
	No		
	Yes, they can be used after renewed informed consent		
	Yes, they can be used without informed consent		
<b>10b.</b>	<b>Can stored research data with personal identifiers be used for another research purpose that requires PERSONAL CONTACT to study members?</b>		
	No		
	Yes, they can be used after renewed informed consent		
	Yes, they can be used without informed consent		
<b>11a.</b>	<b>Have you tried to use data from different EU countries?</b>		
	No		Go to question 12
	Yes		
<b>11b</b>	<b>Did you need permission?</b>		
	No		Go to question 12
	Yes		

<b>11c.</b>	<b>Did you get permission?</b>		
	All EU countries gave permission		
	None of the EU countries gave permission		
	Not all of the EU countries gave permission		
	Please give further information:		
<b>12.</b>	<b>Are your answers based upon? MORE THAN ONE ANSWER POSSIBLE.</b>		
	Personal experience		
	Information from others		
	Reading		
<b>13.</b>	<b>How did you get the questionnaire?</b>		
	From the IEA website		
	From the IEA		
	From my national society		
	Others		

Please describe situations in your country where you think the data inspectorate does not use the directive's facilities for using health data in epidemiological research, or provide any other comments of relevance.

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If you do not mind to be contacted for further questions, please provide your name and e-mail address:

Name: \_\_\_\_\_

E-mail: \_\_\_\_\_

**Please return this questionnaire to:**

**The IEA data directive group**

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