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Legal and ethical issues in conducting Health Examination Surveys (HES) in Europe

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Legislation on ethical conduct of research

Ethical standards must comply with specific legislation, which varies worldwide.

Internationally, the **Declaration of Helsinki** is considered the pillar of ethical standards.

Other important documents include:

- the **Belmont Report** ("Ethical Principles and Guidelines for the Protection of Human Subjects of Research")

- two acts of the Council of Europe:

i) the **Recommendation of the Committee of Ministers** No.R(90) 3 concerning medical research on human beings

ii) the **Oviedo Convention** on Human Rights and Biomedicine.

The FEHES Survey

We investigated how European countries have addressed **ethical and legal obligations** in the **Health Examination Surveys (HES)** conducted to date.

The survey was part of the EU Project **"Feasibility of a European Health Examination Survey" (FEHES)**, whose objective was to evaluate the feasibility of conducting standardized national HESs in European countries.

FEHES was conducted in **2006-2007** and involved **32 countries** (the 27 EU countries, plus Iceland, Macedonia, Norway, Switzerland, and Turkey).

Ethical concerns in HESs

Our survey focussed on **two fundamental concerns**:

- the **Safeguarding of Privacy**; and
- the **Attainment of Informed Consent**

Although the survey addressed these issues as covered in HESs, they are important for **any research involving humans.**

Safeguarding of privacy

Regarding the safeguarding of privacy, the Declaration of Helsinki states:

"…Every precaution should be taken to respect the privacy of the subject [and] the confidentiality of the patient's information…".

This has become increasingly important, given the **progress in information technology** and the **ease of access to data**.

In Europe, the most important document regarding this issue is "**Directive 95/46/EC** of the European Parliament and of the Council of 24 October 1995".

Informed Consent

Obtaining informed consent is more than just the signing of a form: it is a **process of communication** between the individual and the professional conducting the study.

The **ul**timate goal is that the individual **fully understand** the study's aims and methods and how the data will be used.

This communication process is **both an ethical and a legal obligation.**

Survey on legal and ethical aspects of HESs [1/2]

Our survey consisted of a **questionnaire** on legislation in Europe, in particular:

- Legislation on the **ethical conduct of research** in general (e.g., medical research acts, acts on status/rights of patients, ethical research principles); and

- Legislation on **safeguarding privacy** and the protection of personal data (i.e., "Data Protection Acts" also called "Personal Data Acts")

We also **reviewed the actual laws** for salient points.

Survey on legal and ethical aspects of HESs [2/2]

We requested **copies of the informed consent forms** and the **information material** provided to HES participants and analysed them.

The questionnaire was sent to reference persons in **32** European countries and a high response rate was obtained.

Survey: General results [1/2]

We found **both similarities and differences** among countries in safeguarding privacy and informed consent.

All countries but one have a **Data Protection Act** and require approval by an **ethics committee**.

For informed consent for HESs, the **information provided to participants varied greatly** in terms of detail.

ON A SIDE NOTE:
Network of Competent Authorities of the Health Information Strand of DG SANCO has also reviewed legislation on the protection of health data.

Survey: General results [2/2]

Important issues covered in informed consent forms:

- data confidentiality
- specific tests performed and not performed
- future uses of data
- contact for additional research
- linkage with other registries
- right to provide participant's GP with results
- withdrawal from the study at any time
- obtaining consent from children/mentally impaired persons

Survey: General conclusions

OVERALL, the laws and rules of conduct for ethical research and the processing of personal data are **based on common principles in Europe**.

However, **there are many differences** in safeguarding privacy and obtaining informed consent, at least in the HESs conducted to date.

Recommendations [1/3]

Based on the survey results, we developed **recommendations** on addressing legal and ethical aspects of HESs, including a **model of an informed consent form**.

The recommendations are for the future performance of **standardised national HESs throughout Europe**.

They are available on the **FEHES website (www.ktl.fi/fehes)** and in paper form.

Recommendations [2/3]

Obviously, the existing **ethical standards of research on humans must be respected**. This is the responsibility of ethics committees.

With regard to **safeguarding privacy**, it is fundamental that Data Protection Acts cover at least the following:

- **Access to data;**
- **Exchange of data;**
- **Record linkage; and**
- **Anonymisation procedures.**

Recommendations [3/3]

Regarding **informed consent**, the **key issues** for a HES are:

- Participant's **complete understanding** of the scopes, methods, and use of data and thus **absolute clarity of information**
- Assurance that **participation is voluntary**, **withdrawal is possible** at any time, and **data will be kept confidential**.
- Compliance of the informed consent form with **national legislation** (e.g., access to data, sample storage in biobanks).

FINALLY, Informed consent is an **ethical and legal obligation** and regards both the study's performance and protecting privacy.

Conclusions

Again, we focussed **specifically on HESs** and on safeguarding privacy and informed consent.

However, **any research involving humans must comply with ethical standards**, both in performing the survey and in using data and biological materials.

These standards can vary by individual country.

For more detailed information, please consult the **FEHES website (www.ktl.fi/fehes).**