ANCR

Association of the Nordic Cancer Registries

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The ANCR welcomes WMA's open invitation to comment on the Draft Declaration, and the overall intention of the draft Declaration to protect individuals with regard to personal health data. Data protection as well as the ethical foundation of data processing deserve continuous attention.

The ANCR supports the WMA statement that ongoing improvements in the understanding of diseases and the effectiveness, efficiency, safety and quality of preventive, diagnostic and therapeutic interventions can be significantly accelerated through research using data from health databases and biobanks (point 6 of Draft Declaration).

However, the ANCR does not find the Draft Declaration adequately nuanced or detailed to encompass "any use of health data beyond the individual care of the patient", as set out in point 5 of the Draft Declaration.

Data flows are highly complex in modern health care systems. Various qualities of data as well as multiple purposes of data processing require a nuanced approach to collection, storage, use and reuse of data - without compromising individuals' right to integrity, autonomy, privacy and confidentiality.

The ANCR urges the WMA to take into account our comments on:

1) The importance of high quality data for registry-based research and quality control
2) The ethical foundation for data processing – a basis that goes beyond the dichotomy between explicit consent and anonymous data
3) The ethical responsibility of addressing future health care challenges.

Epidemiological research will terminate if the Draft Declaration would be adhered to. The Draft Declaration must be rewritten as the legitimate use of health data extends beyond clinical care and research. This implies that:

- **Anonymous or pseudo anonymous data are *not* preferable to identifiable data and cannot be satisfactory for the purpose of a health database**

- **The codes of conduct in medical and in epidemiological research should be considered separately**

- **The legitimacy of weighting practicability, or feasibility, in deciding whether it is necessary to seek consent for retrospective studies should also be endorsed with the WMA declaration**

- **The definitions in the Draft Declaration needs thorough clarification or they leave room for interpretation.**

Best Regards,

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The importance of high quality data for registry-based research and quality control

The importance of health databases for planning, management and evaluation of health care systems has been shown repeatedly during the last 50 years. Complete and unbiased population-level analyses on routinely collected, individual data concerning health and personal characteristics can address significant concerns about risk factors for disease and provide sound evidence about public health and the effectiveness of health care systems.

Registry-based research has examined an extraordinary range of important questions and thus provided evidence for policy interventions:

- The predictive use of cancer screening programmes
- Shifts in bacterial antibiotic resistance
- The correlation between MFR vaccination and autism
- Cost effectiveness of various drug and surgical treatments
- Cancer risk in relation to mobile phone use
- Long term effects of exposure to radiation be it medical, accidental or environmental
- The efficacy of bicycle helmets in reducing head injury
- Assessing equity in patient survival
- Health risks after a severe accident, e.g., nuclear accident or a carcinogenic leakage into drinking water systems
- Correlations between occupation and disease.

The all overriding purpose with public health registration and research is to provide evidence for public health interventions. Policy makers rely on evidence for public health interventions and the data quality is of essence in this respect.

For public health purposes the data quality must be very high to avoid erroneous conclusions that can harm large population groups. Public health can only be protected from health threats if projections on for example the influence of nuclear plants or mobile phones are based on accurate data of the highest quality.

Therefore anonymous or pseudo anonymous data are ***not*** preferable to identifiable data and cannot be satisfactory for the purpose of a health database, as stated in point 9 of the Draft Declaration.

Collection of unambiguous identifying information on each data subject is essential, both in order to maintain the quality of registry data, avoid duplicate registrations to enable follow-up e.g. linkage to death certificates, and for use of the data for research and quality control. It is critical to protect the quality of registry data in this manner.

In some countries, methods are used that mask the identity of the individuals such as encryption or pseudonymisation for data processing – both as security and as confidentiality measure. For some types of studies data can be processed in anonymous form to the researcher. The important thing is that the registry is able to correct errors on the basis of unique identifiers.

Otherwise the percentage of misleading data in the registry will grow over time without any possibility to be corrected. Such data do not suffice for high quality research providing sound evidence. The danger of missing a true risk to public health or infusing a false risk is substantial and will grow.

Guidelines on confidentiality and ethics for cancer registries have existed both for Europe (ENCR) since 1992 and worldwide (IACR) since 1991. The European Guidelines were revised in 2004 and in 2012. A cancer/disease registry must maintain the same standards of confidentiality in handling

identifiable data as customarily apply to the doctor–patient relationship. This obligation extends indefinitely, even after the death of the patient, also when data are pseudonymised.

Reliable methods to ensure privacy and data protection, while also allowing for data linkage on basis of personal identifiers, are available, known and used in registries and research in the EU providing sound evidence on public health. These methods protect against unwarranted identification of single data subjects while allowing for high quality research and quality control.

The ethical foundation for data processing

Protection of personal data has a long history originating from the Nuremberg code in 1947, followed by the first Helsinki declarations by the World Medical Association since 1964, the Belmont report in the United States (US) in 1979 and the Council of Europe convention 108 in 1981.

Some of the basic principles in all research ethics are the individuals' right to integrity, autonomy, and to refrain from participation in research. In the medical research practice this implies that research subjects should never be exposed to a risk in association with a research project without their explicit consent. This practice was advocated following World War II, in part to protect subjects from harm in experimentation and in part from personal data protection regimens based on human rights. It concurs with the duty of medical confidentiality and the need to protect patients, research subjects and personal data remains unquestioned.

It is, however, increasingly acknowledged that the thinking behind explicit consent is premised on the clinical encounter between doctor and patient. In modern health care systems with highly complex data flows, such a form of consent is unlikely to be adequate for all purposes.

The obligation for clinical researchers to acquire explicit consent from their research subjects is a means to ensure that the decision to participate in any medical research is in fact in the hands of the research subject.

In registry-based research, however, there is no risk to the health of the data subjects due to the retrospective nature of epidemiological research, and there in general is no direct contact to the data subjects. Likewise the potential risk of breach of confidentiality or unauthorised use of collected data is effectively kept minimal, and results presented in tabular or graphical format from where no individuals can be identified. On these grounds there is a growing recognition that the codes of conduct in medical research should be distinguished from those on which epidemiological and observational research are based. **The WMA Draft Declaration must acknowledge the differences between medical and observational research.**

Today ethics in medical research are enshrined in different ethical guidelines such as the Helsinki Declaration and CIOMS ethical guidelines. According to both the Helsinki Declaration, Article B 26 and the CIOMS ethical guidelines individual consent should not be required in cases where conduct of the research would be impossible or impracticable, for example in secondary use of subjects' records from large databases. **The legitimacy of weighting practicability, or feasibility, in deciding whether it is necessary to seek consent for retrospective studies should also be endorsed with the WMA declaration.**

For most public health research purposes it is very difficult or virtually impossible to obtain consent from every data subject in the population studied.

Screening and other public health interventions are examples of interventions that would be difficult to monitor and evaluate if the Draft Declaration was adhered to. The extensive data linkages done in the Nordic (and other) countries for public health research would become impossible, both in terms of organization, in the possibility of contacting diseased data subjects and in the cost of obtaining individual consent. Further, requirements for consent renders public health research impossible because attempts to obtain consent from each data subject leads to a well-documented bias of data - generating biased research results.

Ethical review of public health research is currently mandatory in most European countries at either National or regional level, and functions as a safeguard where such research is conducted without the data subjects' consent.

Ethical vetting at National or regional level offers data subjects a guarantee that the use and reuse of their personal (health) data for research purposes is in line with societal values at the given point in time.

In many countries, access to medical care has become a right to all citizens, based on solidarity and sharing of risk. The Draft Declarations strict adherence to the consent tradition leaves no room for this ethics balancing the interests of the single patient against the interests future patients and citizens in general. The information gained in the course of treatment of one citizen can be used to the benefit of others who develop a similar disease, or are at risk of developing it.

Future health care challenges

Policy-makers across the globe face challenges of designing effective and sustainable health care systems, and protecting a growing population from preventable health threats. Population-level analyses are essential in this respect, but it is not sufficiently clear whether the point 19 of the Draft Declarations provides an opening for exemption from the requirement for explicit consent on this matter.

In the absence of sound population based epidemiological research, actions will be founded on anecdotes, small trials and stakeholder interests.

Registrybased research is a rational and cost-effective means to gain new knowledge and scientific results that can be translated into action. Population and disease registries are of incontestable value, and the benefits from epidemiological research will increase even further with personalised medicine, the development of clinical databases and large scale biobanking facilities provided they can be combined and used for large populations. Research can lead to findings into new therapies, diagnostics and methods of prevention.

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