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Officer in Charge,
Health Information Bill Consultation,
Legislation Unit,
Department of Health and Children,
Hawkins House,
Hawkins Street,
Dublin 2.

Dear Sir / Madam,

Please find attached the Irish Medical Organisation's response to the Department of Health and Children's request for opinions on the proposed Health Information Bill. The IMO is pleased to have the opportunity to contribute to the process.

The IMO is the representative body for doctors in Ireland which, in its mission statement, is 'committed to the development of a caring, efficient, and effective Health Service.' The IMO believes that the Health Information will play a vital role in the development of evidence-based medicine, the management of public health issues, and the fight against chronic diseases and diseases of lifestyle.

Yours faithfully,

A handwritten signature in black ink that reads 'Joseph Richardson'. The signature is written in a cursive style and is positioned above a horizontal line.

Joseph Richardson

Manager – International & Policy Units

OVERVIEW

The Department of Health and Children (DOHC) has launched an open consultation on the Health Information Bill. The DOHC has issued a Discussion Paper on the Proposed Health Information Bill in June 2008. The following is a response to the issues raised in the paper.

THE PRINCIPLES WHICH MUST UNDERLIE THE ACT

The Health Information Bill must be inspired by a series of principles which protect the privacy and confidentiality of the patient while allowing legitimate use of data for research purposes.

Consent

The consent of the patient or data subject must be sought, and re-affirmed where necessary, for the use of data in a fashion other than the direct therapeutic setting in which it was first obtained. The protection of privacy is a fundamental principle. Situations will arise where research for the common good may require the secondary analysis of routine datasets. All such data must be de-identified before analysis. The Bill should stipulate a role for a Research Ethics Committee in considering requests for epidemiological analysis of datasets where express consent has not been obtained.

Control

The data subject must have ultimate control of the data and the right to withdraw consent if desired.

Constraint

There are ethical, technical, and legal constraints on the use of data which must be observed in order to preserve the privacy of the data subject's information.

BENEFITS TO PATIENT SAFETY & CARE

The collation of data from multiple subjects is a recognised method for the development of medical knowledge, the management of disease and of health service planning. The development of evidence-based medicine requires the collection, collation, and analysis of multiple data sets from a significant number of people to provide the basis for medical treatments. The creation of this evidence base should be a major goal of the Health Information Bill. It must facilitate this necessary work. The bill

must recognise that the aggregation of such data gives great power to the aggregator. The Bill must contain safeguards for the individual data holder and provide for efficient oversight of the aggregator of data.

UNIQUE PATIENT IDENTIFIER

The use of a unique identifier is a prerequisite of an efficient health information system. Since it is one of the most powerful tools of any informatic system, it must be handled in a clear, fair, transparent, manner in which the patient's rights are respected at all times. Since the use of such an identifier gives huge power to the agency holding the information it is imperative that the burden of proof in any dispute between the patient or citizen and the agency involved should be placed firmly on the agency not the patient.

The New Zealand experience indicates that the introduction of the unique patient identifier should be accompanied by a similar health professional identifier which would enable the restriction of access to information to appropriate professionals. Access to the patient identifier must be restricted to authorised and registered health professionals who carry their own health practitioner identifier so that all access to data can be tracked.

The database of unique patient identifiers should not contain personal clinical information so that any breach in security regarding healthcare or health professional identifiers can be minimised. It should however allow for clinicians to be alerted to potential difficulties such as allergic reactions.

PARTICIPATION

The issue in question here relates to where the balance of justice lies; in other words, should it be for the state to justify the necessity of participation or the individual to justify the desire to withdraw from the system?

There are well established legal parameters for evaluating this question which justify the compulsory participation of individuals in national data bases in cases of 'notifiable' diseases. There also exist the

data protection laws and regulations. The Health Information Bill should build on the current law and precedents in this area.

The principle of active consent should be built into any regulations regarding participation in the national data base.

The security of any national health records system must be the most important factor in deciding whether or not to run a centralised or decentralised system.

DEVELOPMENT OF REGISTERS

The development of specific registers which capture data relating to specific classes of morbidity should follow as far as possible the general regulations established under the Health Information Bill. All appropriate data should be reported to these registers to increase their value. Should the issue of consent become a problem undermining the value of certain registers, special efforts should be made to encourage the patients to participate. The principle of active consent should, however, be maintained, in relation to all registers unless 'notifiable' diseases are involved.

CONSISTENCY AND CLARITY

There are competing jurisdictions and agencies involved in the area of health information; they include, among others, the Department of Health and Children, the Medical Council, Nursing Board, Health and Social Care Professionals Council and its subordinate Registration Bodies in the regulatory sector; in the research sector, the universities, medical schools, and Health Research Board; in the commercial sector the pharmaceutical and medical devices industries and private health care providers; and lastly the health insurers.

In order to provide consistency between all those with an interest in this area, there should be one central point to which any interested party can apply for clarification or complaint. It would be prudent to appoint the Data Protection Commissioner to act as the point of reference since he has accumulated the greatest level of experience in this area. He should have the role of handling complaints and providing guidance to the individual and to data holders.

COMPREHENSIVE DEFINITION OF HEALTH CARE INFORMATION

It will be important to provide clarity and ease of interpretation for those involved in the Health Informatics. It would be of benefit to have commonly understood definitions which have the force of law; however the prescription of a definition in primary legislation may prove to be both legally and administratively cumbersome. It may be better to build on the current statute law and the experience of the Data Protection Commissioner than to rely on a definition in Health Information Bill.

SENSITIVE INFORMATION AND ITS SECURITY

Information regarding mental health, notifiable diseases, the health information of children and the deceased, among other categories of information, must be treated with special care and be subject to the fullest security safeguards. The unfavourable media comment which occurred over organ and tissue retention

Dr. Joseph Richardson
Head of International & Policy Units