

**Response to the public consultation on the  
Health Information Bill  
by  
The Health Information and Quality Authority**

**1. What are the benefits to patient care and safety which should be the objectives of any legislation?**

The Health Information Bill is a critical piece of legislation to enable the Health Information and Quality Authority to fulfil its statutory obligation in relation to the setting and monitoring of standards for health and social care and for health information. Accurate and timely information is essential for the establishment of a safe, effective and efficient health information management and governance framework. Information in a standardised format should accompany the patient on their journey through the healthcare system. International evidence suggests that the failure to communicate information between care providers at hand-over points is a major contributing factor to adverse incidents. The unavailability of information can lead to delays in patients receiving timely and appropriate treatment and can lead to unnecessary repetition of diagnostic tests and investigations. The importance of health information as a key element in ensuring patient safety and quality improvement has been highlighted in the recently published report of the Commission on Patient Safety and Quality Assurance.

**2. What is the balance to be struck between the right of individuals to control their healthcare information and the needs of those managing healthcare systems, providing healthcare services and undertaking medical research (including the role of Research Ethics Committees) to have limited and controlled access, without individual consent, to such information for legitimate purposes?**

The critical issue in establishing the balance between the rights of the individual to confidentiality of their health information and the legitimate needs/obligations of managers, providers and indeed of the Health Information and Quality Authority, to use that information for legitimate purposes is whether that information needs to be personalised. Except in exceptional circumstances e.g. when conducting an investigation, the Authority does not require access to individually identifiable health information. The same is true for many secondary uses of health information. Therefore the most effective way to balance the individual versus the public good is to ensure that identifiable information is only shared beyond the confines of the healthcare delivery system in exceptional circumstances. De-identification would include the removal of all individually identifiable data including the unique health identifier. In order to support longitudinal linkage of records, the unique identifier can be replaced by a separate study number with the mapping between the two being carried out by a trusted third party or equivalent.

The Data Protection Commissioner has provided helpful guidance to researchers, indicating under what circumstances explicit consent is required. See [http://www.dataprotection.ie/viewdoc.asp?m=m&fn=/documents/guidance/Health\\_research.pdf](http://www.dataprotection.ie/viewdoc.asp?m=m&fn=/documents/guidance/Health_research.pdf).

**3. What rules should accompany the introduction of a Unique Health Identifier for both patients and healthcare providers? In particular, what factors should influence the regulation of the collection, use, disclosure and linkage of such an identifier?**

The National Health Information Strategy (2004) and the Commission on Patient Safety and Quality Assurance as well as many individuals and agencies have advocated the introduction of a unique identifier for healthcare. In the first instance it is an essential element in a safe healthcare system, and in the second it greatly increases the value and usefulness of as well as ease of collection of health information. For example, the ability to link together episodes of care for an individual patient across the entire HIPE data set would significantly enrich the

data set and facilitate much more sophisticated data analyses. This in turn could inform safety and quality improvement initiatives. The Authority also considers that a unique identifier for healthcare providers, both individuals and organisations, is required to ensure the correct identification of individuals with responsibility and accountability for the provision of care. In both cases the use of the identifiers must be carefully circumscribed and confined to purposes of delivering services to the patient. The Authority and the HSE are currently developing a set of recommendations concerning the introduction of a unique health identifier. It is expected that this work will be completed in time to inform the drafting of the Bill.

**4. What legal issues need to be considered in establishing a National Electronic Health Records system: especially as regards an individual’s choice to participate or not and his or her control over the extent of any participation?**

The nature of a National Electronic Health Record (NEHR) is yet to be determined. The legal implications could be different between, for example, an emergency/summary record and a virtual cradle-to-grave comprehensive record, the latter having the potential to be significantly more complex. The Authority considers it appropriate for explicit consent to be required from individuals to participate initially in an NEHR. Thereafter the record could be shared among and viewed by those health professionals directly responsible for delivering care to the patient. Individuals should also have the right – based on informed consent – to exclude or hide (“sealed envelope”) portions of the record from access by others. They should also be permitted to withdraw their participation in the national scheme at any time. Finally, they should be able to see who has accessed their record at any stage.

**5. What principles should guide the development and regulation of National Health Population Registers, such as the National Cancer Registry, and the instances in which reporting to such registers should be mandatory?**

The fundamental principle underlying registries is that as far as possible they

should be populated directly from existing information systems. They should be integrated into the existing national health information framework rather than as stand-alone systems requiring independent data collection processes. The availability of a unique health identifier will greatly facilitate the construction and maintenance of these registers, whether or not they contain individually identifiable data. In the case where it is not necessary or appropriate to contain individually identifiable data, the unique health identifier can be mapped by a trusted third party or some other means into a registry identifier so that records relating to an individual can be linked.

**6. What needs to be done to provide consistency and clarity in and between legislation, other legal rules and professional ethical codes in the treatment of personal health information having regards to considerations of privacy, confidentiality, consent and security?**

Specific protocols and guidance should be developed by the stakeholders to assist in ensuring consistency and conformance with the legislation. Healthcare organisations should consider appointing health information custodians/guardians to inform and support those working with health information in order to ensure compliance.

**7. Is there a need for a comprehensive definition of personal health information and, if so, what should it encompass?**

It would probably be too difficult to provide a comprehensive definition which clearly defines what is included in the record and what is not. For example, the record could include information on, for example, social circumstances, which is not strictly “health” information but could be important in the context of the management of the patient. For example, the European Committee for Standardization (CEN), defines a health record as “a repository of information regarding a subject of care’s health-related history” without in any way defining the type of information which could be included.

- 8. To what extent do certain categories of personal health information – for example, mental health information and information on children and deceased individuals – require special rules on collecting, keeping, using, disclosing and accessing?**

The Authority considers that it is likely that special consideration will have to be given to certain categories in respect of a number of areas including consent.

- 9. Should the Health Information Bill be a comprehensive piece of legislation dealing with all the relevant issues or should it build on the legislative framework (data protection and freedom of information) that is already there and working well?**

The Authority strongly supports the option of building on existing legislation rather than creating a stand-alone health information regulatory structure.

### **Other comments**

- 1.** The Audit of Key International Instruments which accompanies the Discussion Document contains an Appendix entitled “Generally accepted principles for handling personal health information”. The Authority agrees in the main with the principles as outlined but in addition makes the following observation:

The reference to “storing sensitive data on a laptop computer” should be extended to incorporate any information on an external or removable device, irrespective of whether it is on- or off-site.

- 2.** The proposed EU Directive of the European Parliament and of the Council on the application of patients’ rights in cross-border healthcare could have implications in

relation to the sharing of information across borders.

3. Family members/next-of-kin/carers are typically and routinely updated on a patient's condition. It may be necessary to make explicit provision in the Bill to allow for disclosure of health information under such circumstances.
4. Consideration should be given to include an explicit statement in the Bill prohibiting the sale of health information except in the circumstances where a healthcare practice is being sold to another practitioner.
5. Consideration should be given to making provision in the Bill to mandate the use of nationally agreed health information standards, which will be established by the Health Information and Quality Authority, for the sharing of health information.