How can legislation facilitate health research?

Irish Health Research Forum Presentation

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INTRO – Great pleasure to be here. At the last meeting of the Irish Health Research Forum on researcher's careers, in which I participated in a panel discussion, it was my second morning in my new role!

For those who may not know, I am heading up a new function within the Department of Health on Research & Development and Health Analytics. I benefitted greatly from my involvement in the previous forum and hope to learn more today about how legislation can facilitate health research.

My appointment and the broader reforms underway within the Department and across the wider health services provides us with an opportunity to clarify our national objectives in health research and to ensure that the legislation in place supports dynamism and excellence in Irish health and social research.

I am still on a very steep learning curve in my new role and I am especially grateful to my colleague, Peter Lennon, on whom I and my colleagues rely for guidance and direction in advancing the legislative programme for health information and for health research.

The first point I would make is that legislation is never an end in itself. It is an output from the policy development process intended to help achieve a desired outcome. Accordingly, before the legislation, there must be the policy development and analysis.

Consultation, which must include stakeholders and the wider public, is always important in policy development in order that all the issues, all the views and all the options can be established and worked through so as to the arrive at the best policy choice.

In giving effect to the best policy choice, legislation requires clarity about what is intended and certainty about what is being done. For example, definitions in any legislation, are in many ways the key aspect of the Bill because if they are inadequate or inappropriate this will directly impact on what the legislation is seeking to achieve. A good starting point, therefore, may be to define what exactly we mean by "health research".

In developing the policy that will underpin any legislation in the health research area the first two considerations that the Department of Health faces are -what is the present situation and why do we need to change it. So what is the present situation regarding legislation and health research in Ireland?

There is not a great deal of legislation and that is not necessarily a bad thing. Legislation as well as being enabling can also be inflexible where flexibility is desirable to meet new challenges. One thing we do have is the legislation that established the Health Research Board and set out its functions. The Board plays a central and critical role in the promotion of health research in Ireland both directly and indirectly and would be very relevant to any proposed changes in this area.

We also have a Health Identifiers Act that will allow for unique identification of individuals and health services providers for relevant health related purposes. This highlights the interconnection and the interdependence of policies and practices in health information and in health research.

Apart from the above laws, there is not much specific legislative activity underpinning health research. There are the Statutory Instruments that transposed the EU Directive on Clinical Trials on Medicinal Products. Those Instruments led to the creation of recognised RECs for the purposes of clinical trials. There is now a new EU Regulation in the clinical trials area and that may be the impetus for change.

There are also the Data Protection Acts that govern the processing of personal data including for health research. This is also an area where there is a new EU Regulation which will very definitely have implications for health research. Those implications will need to be fully teased out – because the absence of clarity on issues of data protection is undermining advances in health information and progress in health research.

There is no legislation that governs every aspect of human health research in Ireland. Is that a bad thing or is it a good thing? That leads to the second question –is it broke and do we need to fix it or put more positively what change, if any, is necessary and desirable or might even be forced upon from the outside by the EU for example?

We do now have the long awaited General Scheme of the Health Information and Patient Safety Bill. It's worth looking at the background to that Bill to see how legislation can take a considerable time and also to see how the Bill changed dramatically over the period of its preparation. It started off dealing with health information only and now it has research and patient safety elements.

Originally, the aim of the Bill was to create a new standalone structure for the processing of personal information in the health sector that would use definitions, terms and concepts readily recognisable by those involved in the health system. The legal advice was that it was not possible to do so because everything had to be consistent with the EU Data Protection Directive. This in turn has evolved over recent years.

The original Bill also had an enabling framework for the creation of a National Electronic Health Records System but the emerging evidence, especially from the Working Group of Member States' Data Protection Commissioners, is that consent for inclusion in a National EHR is the most appropriate option in a democratic society. Again, thinking in this area is evolving

Edward McKone will be talking later this morning about patient registries and one of the most significant information initiatives in the Bill relates to patient registries (called health information resources in the Bill) and data matching programmes. The Bill provides that the Minister will be able to prescribe national health information resources and data matching programmes in certain situations after consulting with HIQA and the Data Protection Commissioner.

On the research side, the Bill responded to calls for a new streamlined research ethics approval framework for health research other than research involving clinical trials on medicinal products which already has its own structure. It's worth noting that the new structure in the Bill is voluntary rather than mandatory. The Bill also provides for a data protection consent exemption in certain cases of health research using patient identifiable information.

On the research ethics side, some may think that maybe we should have a mandatory system or should have gone down a different route from the clinical trials REC model. On the consent exemption, some will undoubtedly feel that the Bill should go further while others will undoubtedly feel that it has gone too far.

This seems a good point to look at something called the "public interest" which is often found in legislation as a reason for justifying some legislative provision that permits something that would otherwise be prohibited. Health researchers would understandably claim that research that benefits society and individuals is in the public interest. That is certainly a fair argument.

However, our courts have held that privacy and confidentiality are important to patients' trust in the health system and their willingness to access health services when they need them. The public interest also requires the protection of that trust. The big question then is finding a balance that allows valuable health research to be carried out while at the same time not compromising an individual's right to know who is using his or her personal information and for what purposes.

This leads on neatly to the new EU Data Protection Regulation. During the course of the negotiations on the Regulation, we saw the Parliament take a very different view from the Council on health research and the need for consent. The final agreed version of the Regulation is much more health research friendly than the Parliament text.

It will be very interesting to hear what Beth Thompson has to say on the impact of the new EU Data Protection Regulation. However, without jumping into her subject area, it is important to make a few points about the Regulation's relevance to policy making and legislation in this country.

First, this Regulation is actually a hybrid between a conventional EU Regulation and a Directive in that it gives Member States significant flexibility in certain areas, including health research, to introduce their own legislative rules for the processing of personal data.

The Department of Justice and Equality is working on a new Data Protection Bill that will have general applicability. The Department of Health and other government Departments will have to analyse the Regulation to identify what sectoral legislation needs to be introduced. The time frame for carrying out that analysis, preparing any legislation and then enacting it is two years.

I should also point out that the Data Protection Regulation is only one element of a broader legal framework affecting health research. The Constitutional right to privacy continues to be relevant. The common law duty of confidentiality continues to apply as does the European Convention on Human Rights.

By way of a final comment, legislation supporting health research will work best where it enjoys the support of all parties having a stake. That places an onus not just on the Department but also on the research community to build public confidence in health research, its benefits and its governance especially with those that genuinely consider that any special treatment for research poses a risk to privacy and confidentiality.

Unanimity may not be possible given the differing perspectives involved but engagement is the best way to reach consensus and transparency must be a core principle.

So once again, I wish to thank the organisers for involving me in this event. I look forward to learning from other speakers and from the general discussions at the forum on the critical role that legislation can and does play in facilitating health research of the highest calibre.