IPPOSI

ANNUAL ROUNDTABLE MEETING WITH THE SECRETARY GENERAL OF THE DEPARTMENT OF HEALTH

“HEALTH INFORMATION”

June 2014
INTRODUCTION

The Irish health system’s management of Health Information was the subject of IPPOSI’s 3rd Annual Roundtable Meeting with Dr Ambrose McLoughlin, Secretary General at the Department of Health. There was such a high level of interest that IPPOSI had to change venue to accommodate a bigger audience. With representatives in attendance from our patient, science, clinical and industry membership, the issue is clearly one of critical importance to the health community across the board.

There are several reasons for this. IPPOSI members want Ireland to be a world-class deliverer of healthcare where research is part of the everyday culture in our hospitals and healthcare facilities. This means the most up to date and appropriate health information systems and technologies must surely play a part. The Government is in the process of passing laws to accommodate such advances, while within the HSE, groups are working together to continually improve data use to drive better patient outcomes.

The research community and medical research charities want to work with data sources to provide real benefits for Irish patients. Registries, for example, provide all health researchers with the data and clinical information to encourage the development of innovative interventions and the measurement of effectiveness of any given treatments. In some cases they can map the specific genotype profiles of a disease within a given population, and in the era of personalised medicine, they can provide opportunities for our patients to participate in clinical trials or access to new treatment.

At the heart of all this lies the patient.

In this context however, that is not a political sound bite, or an aspirational rallying call. It is a structural fact. The patient is so bound up in health information because health information is patient information, and the health community including those who manage our health service cannot access this information – and deliver the many benefits referred to in this report – without obtaining the patient’s consent to use their information. This bind reveals a tension that permeates every facet of health information:

People universally agree that health research is a good idea – but this does not lead to widespread sharing of information.

This doesn’t apply to all groups, indeed people with serious, chronic and rare conditions are advocates for the importance and benefits of making your medical history available to researchers.

Beyond these groups however, the picture is far less definitive. Data protection in wider society isn’t only – or even chiefly – concerned with health matters. As we shall see, the EU’s Directive from 1995 didn’t even mention healthcare. Today, in an information-rich society dominated by the Internet, where multinational companies, and governments are accused of abusing personal information, public trust is at a low ebb, even as the great majority of people seem unmoved about their emails being monitored, or their photographs and private details shared.

The thrust of emerging data protection policy is to strengthen certain aspects of individual rights. However as the Data Protection Commission point out, the right to data protection by an individual is not an ‘absolute’ right. There are many legislative exemptions whereby data protection rights are overruled by public interest. Nevertheless the position of health research and related exemptions appears to be threatened by proposed amendments to the Data Protection Regulation in Europe, and this fact, coupled with the lack of institutional trust held by populations, presents a major challenge for the implementation and efficiency of eHealth policy and health research in the coming years.

This document begins by examining the policy context for Health Information in Ireland, and for this we are indebted to the contributions of Dr Ambrose McLoughlin, Secretary General of the Department of Health; Mr Peter Lennon, also from the Department; Mr Garrett O’Neill of the Data Protection Office, and Professor Jane Grimson, interim CEO of HIQA.

The European context was provided by Mr Paulo Silva of the European Commission, and the potential problems of the impeding Data Protection Regulation were directly tackled by the CEO of the Health Research Board, Dr Graham Love.

Finally, ongoing developments in eHealth and health information on the island of Ireland were showcased by Dr Shane McKee of the Belfast Health & Social Care Trust; Mr Doug Beaton from the HSE’s Health Intelligence team, and Dr Dmitri Wall of the Irish Skin Foundation.
HEALTH INFORMATION IN IRELAND

The Department of Health acknowledged, in line with sentiments expressed by others throughout the day, that everyone wants a modern integrated health system that delivers enhanced patient care and a better functioning health system. Some of the building blocks for this vision are already in place, including the eHealth Strategy and the upcoming appointment of a Chief Information Officer. Other foundational elements are being written into law, but before giving an account of how the Health Identifiers Bill and the Health Information Bill would speak to these objectives, Peter Lennon of the Department of Health outlined some of the challenges associated with Health Information.

Challenges

Expectations – which are very high. But legislation alone cannot provide the solution. Laws must be backed up with enforcement. Equally, not everything is achievable, or realistic.

Diversity – The health system is diverse, and fragmented. Co-operation isn’t always easy, or straightforward.

Human – people within the health system bring two perspectives: their organisation’s view – and their own. This reflects the tension between the acknowledged need for health research and the reluctance of people to make their health information available (depending on their situation). You have to get people on side. Furthermore, in times of change, people can adopt more entrenched positions, so it is vital to engage with people and build trust.

Requirements vs technology – sometimes the technology runs the agenda rather than the requirements that the technology was sourced for. Technology is an enabler (provided it is appropriate), not a solution.

Trust – People are reluctant to trust organisations with their data, which is understandable in light of revelations about surveillance and data sharing between multinational companies and state security agencies. Trust and openness is vital, as the negative experience of the NHS in England shows. Data Protection itself arose in the aftermath of the Nazi holocaust.

Legal – laws surrounding the collection and use of data are complex and were not designed with healthcare in mind. The laws are there to (1) give guidance to data controllers on their legal responsibilities and consequences for not doing so and (2) protect against unauthorised secondary use of personal data that is unknown to the data subject.

Some or all of these challenges exist in every element of Health Information, in Ireland and in other jurisdictions. Turning now to measures Ireland is taking in this area, the Health Identifiers Bill is due to be enacted very soon.

The Health Identifiers Bill

The primary purpose of the Unique Health Identifiers is to improve patient safety by reducing patient identification errors. Because of the other (secondary) possibilities that exist around Unique Health Identifiers, this can be forgotten.

That said, Unique Health Identifiers are also central to the development of eHealth systems, and they can also be a key to unlocking patient records, however this is fraught with difficulty due to Data Protection issues. So it remains important to remember that their primary purpose is patient safety, not health research. The Troika were also a driving force for the Bill, which it saw as assisting with cost containment objectives, particularly in the area of e-prescribing.

Given that the rationale is patient safety, there is no ‘opt out’ provision in the Bill, and every individual will be given a number. However the Bill does provide for health service delivery in the event that individuals have not or choose not to use their Unique Identifier Number. The Bill also includes provision for criminal offences to deter inappropriate behaviour.

The Bill accounts for approximately 25% of the Department of Health’s work in Health Information (the other 75% being the Health Information Bill), however the Department cautioned against seeing this as an end in itself. Meanwhile the experience of other countries shows that the most important factor is a measured implementation campaign, because if you get implementation wrong at the start, errors are extremely difficult to correct and the Australian experience was cited as an example of this.
The Health Information Bill (& Research Ethics)

This Bill will strengthen the rights of patients, who will for the first time have a right to their medical records. It will also make the purchase or sale of patient records a criminal offence. The Bill will include further patient safety initiatives, especially in the areas of patient disclosure, clinical audits and administrative reporting.

The Health Information Bill provides for a Standards Based Approach to Interoperability so that data can be shared across organisations without encountering compatibility issues. This also speaks to the Prescribed Health Information Resources / Data matching programmes. The Bill is not a stand-alone piece of legislation as was originally intended. While the Department wanted the Bill to recognise concepts that people within healthcare recognise, a legal doctrine created a barrier. A new piece of legislation cannot purport to do what an existing law already does, so the Health Information Bill was built on the edifice of the Data Protection law.

The Bill will streamline Research Ethics approval. This point was welcomed and reinforced by the interim HIQA CEO, Professor Jane Grimson, who echoed the need to make more effective use of research ethics committees in the broader health research area.

The Bill also expressly provides for Data Protection consent exemptions in certain exceptional situations, however we shall see later in this report how difficult such exemptions may be to obtain, both at a national level via the Data Protection Office, and potentially at the European level, following amendments made to the impending draft Data Protection Regulation by the EU Parliament. This issue is very much a live one at European level, where the legislative process is conducted through the EU’s Trilogue – the Commission, Parliament, and Council (of Ministers). At present the matter rests with the Council.

Before getting into the details of this issue however, it is helpful to have a clear understanding of the nature of personal information in Ireland, which the Department of Health, and the Data Protection Office provided.

Personal Data & Data Protection

Peter Lennon of the Department of health said:

“The issue of who actually owns the personal health data in medical records was settled at common law. It belongs to the person or healthcare provider who created the record and not the patient.”

In Ireland, the whole question of ownership was previously moot, as data protection law in this country addressed issues of information control, which meant questions of ownership never arose. This position is unstable however, as questions of intellectual property rights in the UK and elsewhere arise. In America, patient property rights recognise that personal data belongs to the patient – and that parties seeking access to this information should pay the patient for it.

In all cases, and for practical purposes during healthcare interventions, issues of information access are superseded by the ‘circle of care’, which is a concept that recognises that a healthcare provider can and should collect, or access, your information when the delivery of care to you is their objective. Those tests, procedures and treatments (and their results) that address your health issues fall within this circle of care.

Data Protection issues arise when personal medical information is used for secondary purposes – i.e. health research, or is sought by third parties. In this event – and despite provision for exemptions in the upcoming Health Information Bill – a patient’s express consent must be obtained before their information can be shared with a third party, or indeed used by the data holder for non-primary (i.e. non-‘circle of care’) purposes. This reality is regulated by three factors.

The common law duty of confidentiality placed on all healthcare professionals

Professional rules of ethical behaviour

Data Protection legislation

The Data Protection Commission (DPC) maintains that something which is often forgotten about Data Protection legislation is that the whole purpose of the law is for individuals – not charities, interest groups, researchers, or healthcare providers. The key part of the Act is that people must know what you are doing with their data – what your purpose is in keeping it, how you maintain it, process it – and it is their right to get a copy of all their information from you at a low cost to themselves.

The DPC acknowledged that there are instances where the public interest has a ‘majority rules’ effect, and that exemptions may be made, however this was balanced by the precariousness of personal information management, and examples were provided of how a single valid complaint (the DPC does not deal with vexatious complaints) could cause a systemic collapse, even for organisations that have considerable and wide-ranging powers.

At its core, there is no getting around the issue of consent, according to the DPC, but the Commission recognises the value of patient registries and health research, and it works with many organisations on a case by case basis to help them establish such registries because the issues are so complex, and there is no one size fits all solution – no template that can be applied. Mr Garrett O’Neill of the DPOC was quite clear however that there is no escaping the issue of consent.

The Department of Health acknowledged that anonymisation is often suggested as the solution to the consent problem, but there are questions about how effective anonymisation is, in light of emerging sophisticated de-anonymising techniques. The DPC cited a 2007 paper it published on anonymisation, however this was qualified as being potentially out of date in light of the pace of technological change.
Background

In Europe, the position on Data Protection is based on a Directive made in 1995. The EU has since recognised that this Directive (which does not mention health information) is not suited to the more modern challenges presented by an information-rich world. Consequently the Data Protection Regulation will replace the 28 national sets of member state rules with one set of rules. At the same time it will strengthen the rights of individuals and do away with cumbersome requirements, such as reporting notifications to Data Protection supervisors. The Regulation will provide for stronger sanctions, and crucially it will apply to non-EU countries whose companies provide goods and services in the EU. Overall it will mean more control for people over their own data.

Summary (general):
- An enhanced ‘right to be forgotten’
- More transparency about data processing
- Consent to be given explicitly, whenever required
- Strengthened national Data Protection Agencies
- Sanctions with teeth – up to 2% of annual worldwide turnover for companies found to be in breach

Health information in Europe

While the 1995 Directive made no provision for health information, the Data Protection Regulation drafted by the European Commission makes two references, in Articles 81 and 83. You can review the Regulation proposed by the European Commission (Articles 81 & 83) and the amendments proposed by the European Parliament in the appendix.

The EU Parliament amendments were described by Dr Graham Love of the Health Research Board as ‘alarming’, and Dr Love was clear in his desire to raise awareness of these amendments and their implications among the health research and indeed wider health community.

The original draft of the Regulation set out a mechanism for protecting privacy while enabling health enhancing research to continue. The specific and explicit consent for the use and source of personal data is required, but there is also a provision for research exemptions, subject to safeguards in Article 83. This is what the European Commission set out in early 2012. The EU Parliament Amendments significantly reduce the scope for research exemptions, says Dr Love.

The amendments would make exemptions extremely difficult to obtain in practice. The Parliament also deleted the reference to patient registries entirely. The view was expressed that the adoption of these amendments could make research ongoing today illegal, and if not illegal, then from a practical point of view, virtually impossible. In light of this interpretation, the Health Research Board called for lobbying at a European level to neutralise these amendments.

The new Regulations also initially included proposals for “the right to be forgotten”, but these were subsequently excluded as being extremely difficult to implement. The European Court of Justice in the Google decision has now pre-empted the proposed Regulations by stating that there is a right to be forgotten. This will require the regulations to be reviewed again by the Commission, and Parliament and so on.

The European Commission’s representative at the meeting, Mr Paulo Silva, highlighted that Parliament’s proposed amendments have to be understood against the background of EU citizens raised awareness and concerns on the protection of their personal data in the follow-up of disclosures concerning mass surveillance activities.

Mr Silva stated that the Commission was, for the time being, sticking with its original proposal and he made the point that, as usual in these cases, those parties opposed to the amendment have a chance to lobby for their interests. It subsequently emerged, in a wider discussion triggered by this issue that more than a 100 organisations in Europe had already come together through the stewardship of the Wellcome Trust to address this in Europe. Mr Silva informed that the Council was still discussing the Commission proposal and that member states still have the possibility to submit their own specific views on the subject, including calls for exemptions, where appropriate.

Mr Silva explained that under the current Data Protection Directive (95/46/EC) processing of personal data related to health is authorised, besides explicit consent, under certain conditions “for reasons of substantial public interest” which are for Member States to define. Mr Silva explained
that the Commission proposal obliges Member States to ensure specific safeguards for the processing of personal data concerning health, which can be lawful without the explicit consent of the data subject, and sets out specific conditions for processing personal data for historical, statistical and scientific research purposes.

In terms of lobbying process, Peter Lennon of the Department of Health pointed out that the lead Department for Data Protection was the Department of Justice, and that the Department of Health had made vigorous representations to the Department of Justice on these matters, but that if an organisation wished to raise similar or new points around these issues, then his Department would facilitate such moves, though perhaps the window of available time for this was small.

Discussion and debate

The European Parliament amendments issue was a contentious one, leading to a chorus of concern among the meeting’s attendees. The specifics of the amendments are outlined above however wider research concerns stemming from the amendments, and for the whole area of data protection, were expressed.

One speaker questioned how much protection individuals were really receiving if, in having their personal data so closely guarded, their health status was negatively impacted because it was no longer possible to do health research and develop new treatments. Indeed one attendee queried if the issue of consent and data protection had ever been the subject of a health impact assessment.

A representative of the research ethics community also queried the potentially new barriers to obtaining consent exemptions. The person stated that researchers were faced with the deterring prospect of seeking an exemption – which they described as being very challenging – or the near impossible task of obtaining individual consent, and that this would result in either no answer at all, or, based on the challenges of obtaining enough consent, invalid answers from a skewed or inaccurate sample to begin with.

The Data Protection Office highlighted the draconian consequences of non-compliance with data protection rules, which can see cases elevated as far as the European Court of Justice. The DPO reiterated that there was a preference in favour of the rights of the individual over groups and organisations, even those whose intentions ultimately benefit society.

Professor Jane Grimson of HIQA suggested that the answer might lie in a ‘trusted third party’ where anonymisation, and the use of Unique Health Identifiers, data sets, and specific research needs could be used to create new, fully anonymised research identifiers that could be made available to the applying researchers. Meanwhile Peter Lennon highlighted the fact that the Individual Health Identifiers Bill does not change the existing Data Protection law and was not designed to provide linkages with data.

This broad debate prompted one participant to emphasise the need to inform the wider public about these issues – that if Ireland wants to have a world class health system it needs to have world class research, and for that to happen, people will have to understand how important it is for them to make their personal medical information available for health research. Consent should be the norm but the public should have the opportunity to choose to opt in or out. Some countries like the UK chose an opt-out others like Australia chose an opt in, we need to have a public debate about what’s best for Ireland.
With key pieces of legislation in train, and an eHealth strategy launched, what else is happening on the ground in Ireland in terms of health information? Three of the meeting’s panellists spoke to this.

Dr Shane McKee (Northern Ireland)
Doug Beaton (HSE – Health Intelligence)
Dr Dmitri Wall (Irish Skin Foundation)

Dr McKee described the introduction and roll out of ‘Electronic Care Records’ (ECR) across the Northern Irish Health System, and the benefits that this has had for patients, clinicians and administrators in its first year of use.

At the forefront of this is a noticeable improvement in patient / doctor interactions due to two main factors:

Patients – particularly those with rare conditions or multiple conditions – no longer have to spend ten minutes describing their issues, concerns, or most recent healthcare interaction to the clinician in front of them. Every interaction with the health service is attached to the patient’s record.

Doctors don’t have to look for records, or have their heads down reading records during the consultation. The net effect of this is a better quality of interaction that will hopefully translate into improved outcomes.

In establishing the ECR, there were major legacy issues that had to be overcome – approximately 1,700 systems had to be incorporated. So they used patients’ Health Identifiers to populate a master system that could validate every patient within each system, as most systems have a field that can accommodate the Health Identifier. The system used is called ‘Concerto’ and was developed in New Zealand, and it pulls together and warehouses data from a lot of different systems. The key to achieving this was a clear goal – and the goal in Northern Ireland was the ECR.

So when a patient presents in clinic their Health Identifier number is entered and then all of their encounters with the health system across the region are available. What medicines they are taking, lab results, imaging – all rapidly available. This has knock on administrative benefits as when patients cancel, fail to attend, or present on the wrong day for appointments; previously they could not have been treated due to their records not being retrieved ahead of time. Now it is a matter of a few keystrokes.

Patients have a completely new kind of dialogue with their clinicians, because matters that are immediately clinically relevant are discussed without the need for historical context. Meanwhile there are environmental benefits through saving paper.

Dr McKee believes that patients should have more control of their records. They can see their data on screen – and while clearly the health community in Northern Ireland is very protective of such sensitive information, there does seem to be a shift in thinking here, and this is very much driven by the patients. Patients could perhaps be given access to redacted forms of their records online.

Dr McKee finished by saying that it was early days for the system, which only recently celebrated its first birthday. Nevertheless, within weeks of implementation, note requests fell by 80%. The ambition is to translate these improvements into an improved A&E experience where many challenges still exist.

In the Republic we are still some way from establishing an Electronic Care Record, but that is not to suggest that nothing innovative or effective is happening here in the Health Information space, as Doug Beaton from the HSE explained.

Doug is a member of the HSE’s Health Intelligence Team, which is a part of the Health and Wellbeing Directorate that was established in 2013. The Health Intelligence team’s focus is to make the best use possible of the range of data sources available to it. This is mainly achieved through the Health Atlas Ireland System – www.healthatlasireland.ie. The homepage gives you a sense of the breadth of information contained on the site, though in line with such sensitive information, you will be challenged before you can view it, via a registration process.

Essentially the Health Atlas uses Ordinance Survey maps and CSO, HIPE, and other health data sets to get a picture of the health of the people in every area of Ireland, thereby capturing the performance of health services in those regions. HSE staff have access to a wide range of data about health services locally, which assists them in planning and managing services.

This principle is further developed in the NQAIS – the National Quality Assurance Information System. The Health Intelligence team has worked with the HSE clinical pro-
grammes, and the RCSI and the RCPI to harness HIPE data and help collegiate groups of practitioners look at practices within their own specialities. The simplest example of this would be to display the length of stay time of a clinical team performing an elective procedure in one hospital, versus that of another. This promotes rehabilitation time improvements while striking a balance between efficiency and effectiveness.

The Health Intelligence team have also project managed the introduction of SAT – the Single Assessment Tool project, which puts tablet computer based software system in the hands of nurses and other HCPs to assess the care needs of older people seeking home help and support. Meanwhile the team has also been involved with health registries, and the Atlas is currently being used by IPPOSI chairman, Godfrey Fletcher, for the Cystic Fibrosis Register.

The final panellist to address Heath Information in the Irish context was Dr Dmitri Wall of the Irish Skin Foundation. Working with the Skin Foundation, Dr Wall has sought to develop patient-centred solutions that have the concept of registries, data protection and data utility at their core. He began by expressing his frustration – shared by many in the audience – with poor information processing and the need to repeatedly recount patient stories to health professionals. As a physician, Dr Wall has experience this frustration from both sides, nevertheless he believes that if we can make information useful, connected and personalised, then we can revolutionise care in this country.

This possibility is enhanced, argued Dr Wall, by our genetic homogeneity and also by the fact that we are a well-educated, English-speaking country that attracts pharma and technology investment from multinational companies. In other words, we are the perfect size and make-up to achieve national solutions that could become international models. This is the opportunity Ireland has now, according to Dr Wall.

In his own experience in establishing a patient registry for the Irish Skin Foundation, he is developing in consultation with IPPOSI, Dr Wall noted that registries (in a scientific sense) identify questions that can be answered by collecting defined observational data. It’s about collecting naturally occurring data with a particular purpose in mind. So Dr Wall initially sought to answer two questions:

- Is a registry of Irish Skin Diseases needed?
- If so, how do we create and implement it?

The work behind establishing the registry also sought to answer the most fundamental question: what information, if you had it available, would dramatically change dermatology in this country? Dr Wall found other dedicated stakeholders in dermatology and at the heart of this ecosystem lay the empowered patient who – a patient who, with the right information, could start to gain control of their skin health.

Thus the Irish Skin Foundation Registry keeps the patient at the centre, and seeks to support delivery of the core components of their care while collecting data – both simple and more in depth data. Objectives include the creation of a national dermatology image archive, and a data hub that can deliver back information to patients and their carers. It is hoped that this will support the later introduction of bio-banking and wearable technology, and give patients the chance to relay information in real time thereby creating a better picture of their overall health. This will help demonstrate actual, rather than perceived, impacts of their conditions.

Dr Wall believes trust is vital, that patients must believe that their data is secure and only used for the purposes they consented to, but equally he would like to create the situation where patients are the drivers of their data, ensuring it is utilised to improve their health.
CONCLUSION

This report began by referring to the primacy of the patient, so it is fitting that the final panellist’s contribution held the patient at its core. There is no question of the desire for a modern, integrated and technologically advanced health system in Ireland and, as Dr Wall and others pointed out, Ireland is poised to capitalise on its advantages to potentially become a world leader in health information.

The principle barrier to this is, ironically, the patient – or perhaps more accurately potential patients, who we might refer to more plainly here as ‘people’.

People must be made to recognise that if they want a world class health system, they must reciprocate and make their personal medical information available for research. The Data Protection Commissioner has independent research which shows the majority of the public are willing to provide their consent to medical research provided they are fully informed about the purpose. As such, the DPC suggests that the more information the health community provide, the better the chances of garnering public support.

In the meantime, the health community in Ireland must quickly band together with like-minded organisations in Europe to nullify the European Parliament amendments, and prevent an already difficult job from becoming that much harder again and contribute to the development of novel solutions where they are necessary.
### Article 81: Processing of personal data concerning health

<table>
<thead>
<tr>
<th>European Commission</th>
<th>EU Parliament proposed amendment #191</th>
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<tr>
<td><em>Within the limits of this Regulation and in accordance with point (h) of Article 9(2), processing of personal data concerning health must be on the basis of Union law or Member State law which shall provide for suitable and specific measures to safeguard the data subject's legitimate interests, and be necessary for:</em></td>
<td><em>In accordance with the rules set out in this Regulation, in particular with point (h) of Article 9(2), processing of personal data concerning health must be on the basis of Union law or Member State law which shall provide for suitable, consistent, and specific measures to safeguard the data subject's interests and fundamental rights, to the extent that these are necessary and proportionate, and of which the effects shall be foreseeable by the data subject, for:</em></td>
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<td>the purposes of preventive or occupational medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject to the obligation of professional secrecy or another person also subject to an equivalent obligation of confidentiality under Member State law or rules established by national competent bodies; or</td>
<td>the purposes of preventive or occupational medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject to the obligation of professional secrecy or another person also subject to an equivalent obligation of confidentiality under Member State law or rules established by national competent bodies; or</td>
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<td>reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety, inter alia for medicinal products or medical devices; or</td>
<td>reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety, inter alia for medicinal products or medical devices, and if the processing is carried out by a person bound by a confidentiality obligation; or</td>
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<td>other reasons of public interest in areas such as social protection, especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system.</td>
<td>other reasons of public interest in areas such as social protection, especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system and the provision of health services. Such processing of personal data concerning health for reasons of public interest shall not result in data being processed for other purposes, unless with the consent of the data subject or on the basis of Union or Member State law.</td>
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1a. When the purposes referred to in points (a) to (c) of paragraph 1 can be achieved without the use of personal data, such data shall not be used for those purposes, unless based on the consent of the data subject or Member State law.

1b. Where the data subject’s consent is required for the processing of medical data exclusively for public health purposes of scientific research, the consent may be given for one or more specific and similar researches. However, the data subject may withdraw the consent at any time.

1c. For the purpose of consenting to the participation in scientific research activities in clinical trials, the relevant provisions of Directive 2001/20/EC of the European Parliament and of the Council shall apply.
Processing of personal data concerning health which is necessary for historical, statistical or scientific research purposes, such as patient registries set up for improving diagnoses and differentiating between similar types of diseases and preparing studies for therapies, is subject to the conditions and safeguards referred to in Article 83.

2. Processing of personal data concerning health which is necessary for historical, statistical or scientific research purposes shall be permitted only with the consent of the data subject, and shall be subject to the conditions and safeguards referred to in Article 83.

(2a). Member States law may provide for exceptions to the requirement of consent for research, as referred to in paragraph 2, with regard to research that serves a high public interest, if that research cannot possibly be carried out otherwise. The data in question shall be anonymised, or if that is not possible for the research purposes, pseudonymised under the highest technical standards, and all necessary measures shall be taken to prevent unwarranted re-identification of the data subjects. However, the data subject shall have the right to object at any time in accordance with Article 19.

The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying other reasons of public interest in the area of public health as referred to in point (b) of paragraph 1, as well as criteria and requirements for the safeguards for the processing of personal data for the purposes referred to in paragraph 1.

3. The Commission shall be empowered to adopt, after requesting an opinion of the European Data Protection Board, delegated acts in accordance with Article 86 for the purpose of further specifying public interest in the area of public health as referred to in point (b) of paragraph 1 and high public interest in the area of research as referred to in paragraph 2a.

(3a). Each Member State shall notify to the Commission those provisions of its law which it adopts pursuant to paragraph 1, by the date specified in Article 91(2) at the latest and, without delay, any subsequent amendment affecting them.


### Article 83: Processing for historical, statistical and scientific research purposes

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<th>European Commission</th>
<th>Proposed EU Parliament amendment #194</th>
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<tr>
<td>Within the limits of this Regulation, personal data may be processed for historical, statistical or scientific research purposes only if:</td>
<td>In accordance with the rules set out in this Regulation, personal data may be processed for historical, statistical or scientific research purposes only if:</td>
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<td>these purposes cannot be otherwise fulfilled by processing data which does not permit or not any longer permit the identification of the data subject;</td>
<td>these purposes cannot be otherwise fulfilled by processing data which does not permit or not any longer permit the identification of the data subject;</td>
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<td>data enabling the attribution of information to an identified or identifiable data subject is kept separately from the other information as long as these purposes can be fulfilled in this manner</td>
<td>data enabling the attribution of information to an identified or identifiable data subject is kept separately from the other information under the highest technical standards, and all necessary measures are taken to prevent unwarranted re-identification of the data subjects.</td>
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APPENDIX 1

Bodies conducting historical, statistical or scientific research may publish or otherwise publicly disclose personal data only if:

- the data subject has given consent, subject to the conditions laid down in Article 7;
- the publication of personal data is necessary to present research findings or to facilitate research insofar as the interests or the fundamental rights or freedoms of the data subject do not override these interests; or
- the data subject has made the data public.

The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and requirements for the processing of personal data for the purposes referred to in paragraph 1 and 2 as well as any necessary limitations on the rights of information to and access by the data subject and detailing the conditions and safeguards for the rights of the data subject under these circumstances.

Amendment 195: Proposal for a regulation Article 83 a (new)

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<th>European Commission (NA)</th>
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<td>Article 83a</td>
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<td>Processing of personal data by archive services</td>
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Once the initial processing for which they were collected has been completed, personal data may be processed by archive services whose main or mandatory task is to collect, conserve, provide information about, exploit and disseminate archives in the public interest, in particular in order to substantiate individuals' rights or for historical, statistical or scientific research purposes. These tasks shall be carried out in accordance with the rules laid down by Member States concerning access to and the release and dissemination of administrative or archive documents and in accordance with the rules set out in this Regulation, specifically with regard to consent and the right to object.

Each Member State shall notify to the Commission provisions of its law which it adopts pursuant to paragraph 1 by the date specified in Article 91(2) at the latest and, without delay, any subsequent amendment affecting them.
APPENDIX 2
Contributor biographies

Dr Ambrose McLoughlin BDS, MBA was appointed Secretary General of the Department of Health on 17th April 2012. He has over 30 years’ successful experience in the Health Service from Practitioner Level to Chief Executive. He was previously the Registrar/Chief Executive of the Pharmaceutical Society of Ireland (PSI), the pharmacy regulator; the CEO of the North Eastern Health Board (NEHB) and also the Deputy CEO NEHB, responsible for Acute Hospitals and Community Services. His qualifications include a Masters in Business Administration from University College Cork, a Certificate in Public Administration – IPA and is also BDS, NUI – Dublin Dental School (1974).

Peter Lennon works in the Department of Health. He was formerly Director of the National General Practice Information Technology Project. He has written and lectured on health service management, data protection in the health system, and organisational and information policy failure. He is the author of ‘Protecting Personal Health Information in Ireland: Law and Practice’.

Dr Shane McKee is a consultant and Clinical Lead for Genetic Medicine in the Belfast Health & Social Care Trust, based at Belfast City Hospital. His clinical and research interests centre on the diagnosis and management of rare genetic syndromes causing learning disabilities and birth defects. He is current Clinical Lead for the Belfast Trust in the Northern Ireland Electronic Care Record (NIECR), a regional project aimed at pulling together information from diverse sources into a unified web portal in order to improve patient care.

Professor Jane Grimson is a computer engineering graduate from the University of Dublin, Trinity College, with Masters and Doctoral degrees in Computer Science from the Universities of Toronto and Edinburgh, respectively. She holds a personal chair in Health Informatics in Trinity College and is currently seconded to the Health Information and Quality Authority in Ireland as Director of Health Information and Acting Chief Executive. Her principal area of research is eHealth, focusing particularly on electronic health records and standards.
Mr Paulo Silva represents the European Commission and is presently policy officer at DG JUST – Data Protection Reform. He is also Policy Officer at DG MARKT – Public Procurement, and finally, Legal Counsellor at the Portuguese Permanent Representation to the EU.

Garrett O’Neill is a solicitor and legal adviser in the Data Protection Commissioner’s office. His role includes in-house legal advice, and providing assistance for all types of private sector organisations including corporations, companies, trade representatives and interest groups, on all issues relating to compliance as data controllers with the Acts. Garrett also engages with and advises public sectors bodies such as the Government departments, state bodies, and HSE (among others) on issues concerning data sharing, and new legislation that could affect the data protection rights of individuals.

Doug Beaton is the Management Lead of the HSE Knowledge Management function (incorporating the Health Intelligence team), part of the Health and Wellbeing Directorate. Doug is a Scot, and began his professional life in the field of mental health nursing, holding a number of clinical and management positions in mental health services in the NHS in the UK. Doug holds a Degree in Computer Sciences (Open University), a Masters in Health Informatics (Southampton University), a Masters in Health Services Management (Trinity College Dublin), and a Post-Graduate Diploma in Public Health (London School of Hygiene and Tropical Medicine).

Dr Graham Love (PhD) is the Chief Executive of the HRB. He brings 15 years leadership and senior management experience to the HRB, with his most recent role being Chief Executive of Molecular Medicine Ireland. Previous positions include a variety of senior posts at Science Foundation Ireland including Interim Director General, Director of Policy and Communications and Director of Discover Science and Engineering. During his time at SFI he was responsible for the development of SFI’s 2009-2013 strategy - a €1.1 billion plan to drive delivery of the Government’s enterprise science agenda and its’ successor, Agenda 2020. He graduated with a BSc (Hons) in Pharmacology in 1993, followed by a PhD in vascular cell biology in 1997 from University College Dublin.
Dr Dmitri Wall graduated from medical college in UCD in 2004. He is currently taking time out from the Dermatology specialist-training scheme to work with the Irish Skin Foundation researching the development of a national, connected health system for Dermatology and a Registry of Skin Diseases. He is also undertaking a Master in Health Informatics in Trinity College Dublin. He has publications in the area of dermatology and health informatics and has a special interest in health informatics, registries, medical error and patient-centred care.

Mr Godfrey Fletcher is the Chairperson of IPPOSI where he represents the Cystic Fibrosis Registry of Ireland, which collects and analyses information relating to cystic fibrosis in order to improve the quality of care for all of the people with cystic fibrosis in Ireland. Godfrey is also CEO of Vu2Vu a customer service provider of personal telepresence video conferencing systems. Godfrey is also a steering committee of the European CF Registry and a steering committee member on the HSE CF Working Group. He is also an industry steering member of the Academic Research Centre for Connected Health.

In July 2007, Ms Eibhlin Mulroe became the first CEO of the Irish Platform for Patients’ Organisations, Science and Industry (IPPOSI). Ms Mulroe was appointed by the Minister to the Department of Health Steering Group on Rare Disease Policy in 2010, she represents patients on the HIQA Research Ethics Advisory Board, she is a member of the HSE Patient’s Forum and the patient representative on the Legal Consultative Panel of the Irish Medicines Board. She has a BSc Hons in Politics from Queens University Belfast and is an MBA graduate from the Smurfit Business School, University College Dublin.
APPENDIX 3

Public attitudes to clinical research

Should your Medical Records, be made available for the Purpose of Advancing Medical Research?

*The majority are in favour but, only with permission*

- Yes – but only with my permission
- Yes, without having to ask my permission but only if records are anonymous
- Yes - without having to ask my permission
- Don't know
- No

Base: All